Adverse Experience Reporting Program

Annual report of events occurring in 2015

December 2018
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More information

For more information about the AERP, contact the APVMA:
Phone: +61 2 6210 4806
Fax: +61 2 6210 4840
Email: aerp@apvma.gov.au

How this report is set out

Chapter 1 introduces this report. It defines an adverse experience and explains the APVMA process for assessing and classifying a report of an adverse experience, along with regulatory action or risk mitigation actions the APVMA may take in response.

Chapter 2 explains how to read and interpret information in this report. It is important that readers understand how to interpret data in this report correctly.

Chapter 3 sets out the results of AERP assessments in the years 2015 involving registered Agricultural Chemicals and adverse experiences relating to Humans.

Chapter 4 sets out the results of AERP assessments in the years 2015 involving registered Agricultural Chemicals and effects relating to crops, animals and environment and included lack of efficacy.

Chapter 5 sets out the results of AERP assessments in the years 2015 involving registered Veterinary Medicines products and adverse experiences involving humans.

Chapter 6 sets out the results of APVMA assessments in the years 2015 involving registered Veterinary Medicines and effects relating to animals.

An Index of active constituents and adjuvants are provided at the end of this report.
1 INTRODUCTION

As part of our work to manage veterinary medicines and agricultural chemical products throughout their lifecycle, the APVMA operates an Adverse Experience Reporting Program (AERP). The AERP assists in ensuring that registered veterinary medicines and agricultural products on the market remain safe and effective, are of acceptable quality, and that instructions and warnings on labels are appropriate.

The APVMA assesses and classifies reports of adverse experiences from the exposure to, use of, or the administration of a veterinary medicine or agricultural chemical product sold in Australia. This is vital for detecting uncommon conditions not evident, and therefore not assessed, during clinical or field trials for the initial APVMA registration of a product. It is also used for tracking the incidence of known adverse experiences from some products (particularly veterinary medicines). Anyone can report an adverse experience to the APVMA, including farmers, pet owners, gardeners, veterinarians or the general public.

We assess each report of an adverse experience, and classify the relationship between the veterinary medicine or agricultural chemical product and the adverse experience. As a result of this assessment the APVMA may confirm the registration of a product as safe and effective, or request some changes to how a product is manufactured, packaged or used (and therefore require a change to label instructions and warnings). In some cases, we may cancel registration of a product and remove it from the market.

1.1 Classifying an adverse experience

The APVMA classifies the relationship between exposure to or use of a product and a reported adverse experience in the following terms:

- probable
- possible
- probable or possible off-label
- unlikely or
- unknown.

Probable

All the following criteria are met:

- There is a reasonable association between exposure to or the use of a product and the onset and duration of the reported adverse experience.
- The description of the presenting signs is consistent with, or at least plausible, given the known pharmacology and toxicology of the product.
- There are no other equally plausible explanations (or contributing factors) for the adverse experience.
- When any of these criteria cannot be satisfied (due to lack of sufficient information or conflicting data) the APVMA cannot classify the relationship as probable.
Possible

A possible classification is given when the way the suspect product was used is one of other possible and equally plausible explanations (or contributing factors) for the adverse experience (e.g. a pre-existing condition).

Probable / possible off-label

As per the classification of probable or possible, but also where clear evidence of off-label use exists (including use in species not listed on the product label, over-dosing or under-dosing).

Unlikely

An unlikely classification is given when sufficient information exists to establish that the adverse experience was not likely to have been associated with how a product was used or if other more plausible explanations exist.

Unknown

An unknown classification applies when reliable data are unavailable or are insufficient to make an assessment of an adverse experience.

1.2 HOW TO READ THIS REPORT

This report summarises APVMA classifications of adverse experience reports in table format. Active constituents and species affected are listed in alphabetical order. Presenting signs are listed in alphabetical order.

When active constituents have generated a notable number of reports and/or presenting signs, a brief description of the chemical is provided, along with why that number of reports may be expected, and if regulatory action was considered necessary.

Interpreting the data in this report

There are confounding elements with presentation of the data which should be considered when interpreting data in this report.

1. A registered product may have more than one active constituent.

The adverse experience reported for a particular product may be related to any one or more of its active constituents. This means the number of reports of an adverse experience and presenting signs may be listed under more than one active constituent.

In the example below, a single possible report of ‘death’ associated with a product containing active constituent A, B and C would see ‘death’ listed under each active constituent. It is incorrect to conclude that three deaths were as a result of using that product. Active constituents A, B or C may also be present in other products, so the number of reports and presenting signs for an active constituent may also differ.
2. **An active constituent may be present in a number of different registered products.**

   This means it will have generated a high number of adverse experience reports. This does not indicate that there is a problem with this active constituent.

3. **An adverse experience report may have described multiple presenting signs.**

   This means that adding the number of presenting signs for an active constituent does not provide the number of reports, nor indicate reporting incidences. This is because an adverse experience report may have described multiple presenting signs. In the example below, the three adverse experience reports for Active Constituent A described more than one presenting sign, creating an appearance of more than three reports:

   - three reports described injection site reaction
   - the same three reports also described anorexia
   - two of the three reports also described oedema
   - one report also listed pain.

4. **The number of reports listed under an active constituent gives no indication as to the total reporting incidence of adverse experiences related to that active constituent.**

   This means that data in this report is only a general reference to the types and numbers of adverse experiences reported to the APVMA or product registrants.

   If a report was made for any given active, where the event occurred in 2015, and that report was classified as possible or probable. The active will be included in this report.

   An active may be registered or discontinued during the period of this report. If it was discontinued it is possible that though it is no longer being sold, that there is an amount remaining in the community that has been used.

   **Example**

   **ACTIVE CONSTITUENT A**

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Reports</th>
<th>Total Probable</th>
<th>Total Possible</th>
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<tbody>
<tr>
<td>2015</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

   **Presenting signs (probable and possible)**

   - Anorexia (3)
   - Injection site reaction (3)
   - Oedema (2)
   - Pain (1)
2 SUMMERY OF EVENTS OCCURING IN 2015

2.1 Veterinary

A total of 4064 adverse experience reports involving registered veterinary products were reported to have occurred in 2015. Of these:

- 80 per cent involved animal safety
- 18 per cent involved lack of efficacy and
- 2 per cent involved human health issues (Figure 1).

Of the 4064 adverse experiences reports assessed by the APVMA, 2704 were classified as either probable or possible.

![Figure 1: Adverse experience reports involving registered veterinary medicines that occurred in 2015](image)

2.2 Agricultural

In 2015, a total of 36 adverse experience reports involving agricultural products were reported to have occurred. Of these:

- 33 per cent involved effects on crops or animals,
- 61 per cent involved human health issues, and
- 6 per cent involved effects on the environment (Figure 2).

Of the 36 reports assessed by the APVMA, 15 were classified as probable or possible.
A total of 91 adverse experiences involving effects on humans from registered veterinary medicines and agricultural chemical products were reported to have occurred in 2015. Of these:

- 30 per cent were classified as probable or possible,
- 56 per cent were classified as off-label and
- 17 per cent were classified as unlikely or unknown.
No adverse experience assessed and classified by the APVMA in 2015 required major regulatory action against any registered product.

Under-reporting

The APVMA acknowledges there is likely under-reporting of adverse experiences. The magnitude of under-reporting is unknown and provides limitations in quantifying product risk. For this reason, the APVMA employs control limits that take into account the potential under-reporting of adverse experiences.
3 AGRICULTURAL – HUMAN

This chapter summarises classifications of APVMA assessments of adverse experience reports involving registered agricultural chemicals and effected humans, relating to events occurred during 2015. At the time of publication 36 reports had been received. Human health issues accounted for 61 per cent of these.

3.1 Chemical Review

Chemical reviews are undertaken when there is concern relating to a chemical active. AERP data and trends provide an input to formal reviews of the safety and effectiveness of agricultural and veterinary chemicals.

In the years in 2015 the following reviews were completed:

**Fenthion** is a broad-spectrum organophosphorus insecticide. Fenthion was used to control insect pests in agricultural, commercial and domestic situations and external parasites on cattle. Fenthion was also used to control pest birds in and around buildings. Following the completion of the review of fenthion in October 2014 all active approvals and product registrations were cancelled. Products containing fenthion may not be used or supplied as the phase-out period ended in November 2015.

**Fenamiphos** was nominated for review following reports of bird and fish deaths possibly relating to the use of products containing fenamiphos. Additional reports of adverse experiences involved the potential for environmental contamination of groundwater and waterways, particularly due to leaching from the site of application.

**Dichlorvos** was reviewed because of concerns relating to public and occupational health and safety, the environment, residues and trade. This action was based on reports of adverse experiences, regulatory action by the United States Environmental Protection Agency, and residue violations in cereals and cereal products.

APVMA determined that there was insufficient data for us to be satisfied that there was adequate protection for people in relation to occupational exposure, exposure arising from some domestic uses, and residues in some food commodities. Dichlorvos product labels did not conform to current safety standards and that labels did not contain adequate information to protect the environment.

Accordingly, the APVMA cancelled the registration of one home garden product, cancelled some specific uses (including use for grain fumigation) and required registrants to modify products labels in line with the review findings.

**Azinphos-methyl** review was completed in March 2015. Azinphos-methyl was nominated due to concerns about its toxicity and associated potential risks to the public, occupational health and safety and the environment. There were related concerns about residues and possible impacts on Australian trade. In finalising the review, the APVMA updated the product labels to bring them in line with the current First Aid and Safety Directions Handbook and added a restraint statement prohibiting the use of hand-held sprayers to protect workers.

The information presented in the following section should be considered with regard to APVMA guidance on how to read this report available at Chapter 1.2.
### 3.2 BENZALKONIUM CHLORIDE

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<td>2015</td>
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</table>

Presenting signs (probable and possible)
- Burning sensation (1)
- Respiratory problems (1)
- Oral (burn) (1)
- Sensitivity to chemicals (1)

### 3.3 CHLORINE PRESENT AS SODIUM HYPOCHLORITE

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<td>2015</td>
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Presenting signs (probable and possible)
- Irritation (skin) (1)

### 3.4 COUMATETRALYL

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<td>2015</td>
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Presenting signs (probable and possible)
- Respiratory problems (1)
- Sore throat (1)

### 3.5 IMIPROTHRIN

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Presenting signs (probable and possible)
- Allergy (1)
- Irritation (eye) (1)
- Rash (1)

### 3.6 LAMBDA-CYHALOTHIRIN

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</table>

Presenting signs (probable and possible)
- Allergy (1)
- Malaise (1)
- Respiratory problems (1)
### 3.7 PERMETHRIN

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</table>

Presenting signs (probable and possible)
- Allergy (2)
- Malaise (1)
- Respiratory problems (1)
- Irritation (eye) (1)
- Rash (1)

### 3.8 PICLORAM PRESENT AS THE HEXYLOXYPROPYLAMINE SALT

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Presenting signs (probable and possible)
- Unpleasant taste (1)

### 3.9 PIPERONYL BUTOXIDE

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<td>2015</td>
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Presenting signs (probable and possible)
- QC (1)

### 3.10 POLY (HEXAMETHYLENE BIGUANIDE) HYDROCHLORIDE

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<td>2015</td>
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</table>

Presenting signs (probable and possible)
- Burning sensation (1)
- Respiratory problems (1)
- Oral (burn) (1)
- Sensitivity to chemicals (1)

### 3.11 PYRETHRIN

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Presenting signs (probable and possible)
- QC (1)
### 3.12 Pyrethrum Extract

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Presenting signs (probable and possible)

QC (1)

### 3.13 Sodium Hypochlorite

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Presenting signs (probable and possible)

Irritation (skin) (1)

### 3.14 Triclopyr Butoxyethyl Ester

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Presenting signs (probable and possible)

Unpleasant taste (2)
4 AGRICULTURAL – STANDARD

This chapter summarises classifications of APVMA assessments relating to events in 2015 of adverse experience reports involving agricultural chemicals that are not human cases, and were classified as probable or possible.

In 2015, a total of 36 adverse experience reports involving agricultural products were reported to have occurred. Of these:

- 33 per cent involved effects on crops or animals,
- 61 per cent involved human health issues, and
- 6 per cent involved effects on the environment (Figure 2).

The information presented in the following section should be considered with regard to APVMA guidance on how to read this report available at Chapter 1.2

4.1 (Z)-9 TRICOSENE

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<td>2015</td>
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Presenting signs (probable and possible)

Behavioural change (1)  Lethargy (1)

4.2 COUMATETRALYL

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<tr>
<td>2015</td>
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Presenting signs (probable and possible)

Poisoning (1)

4.3 IMIDACLOPRID

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Presenting signs (probable and possible)

Behavioural change (1)  Lethargy (1)
### 4.4 SODIUM FLUOROACETATE

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<th>Total Reports</th>
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<tr>
<td>2015</td>
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</table>

**Presenting signs (probable and possible)**

- Agitation (1)
- Behavioural change (1)
- Convulsions (1)
- Death (2)
- Incontinence (1)
- Paralysis (1)
- Vocalisation (2)
This chapter summarises classifications of APVMA assessments of adverse experience reports involving registered veterinary medicines and effects on humans which occurred during 2015.

There were 4065 adverse experience events reported which occurred in 2015 involving registered veterinary medicines of which:

- 2 per cent of these reports related to adverse experiences in humans, for example, needle stick injuries (approximately 100 each year).

The variety of products used in animals that are administered by injection includes biologics, vaccines, antibiotics and hormones. The procedure, pharmaceutical and species all impact on the risk to the person administering the product. Accidental injections or product exposures can result in mild to severe injuries and as off label incidents are not presented in this report the frequency of needle stick injury (NSI) is not accurately represented here.

Though severe reactions are not common, serious reports regarding NSI, are received every year. Correct initial treatment will improve the outcome for all penetrating injuries. All concerns regarding exposure should be referred to a health professional directly. It is valuable to present the package or insert at the time of consult, and healthcare professionals should consult the label and manufacturer for appropriate management. They hold detailed information in regard to the actives and adjuvants, they should be contacted in the first instance for information and subsequently to report adverse effects.

The information presented in the following section should be considered with regard to APVMA guidance on how to read this report available at Chapter 1.2

### 5.1 AHC-2102225 (MONEPANTEL)

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<th>Year</th>
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<tr>
<td>2015</td>
<td>1</td>
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</table>

**Presenting signs (probable and possible)**

- Erythema (1)
- Paraesthesia (1)

### 5.2 CAMPYLOBACTER FETUS (VIBRO FETUS)

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<tr>
<th>Year</th>
<th>Total Reports</th>
<th>Total Probable</th>
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<td>2015</td>
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</table>

**Presenting signs (probable and possible)**

- Erythema (1)
- Injection site reaction (1)
- Pain (1)
### 5.3 CAMPYLOBACTER JEJUNI SUB-SPECIES JEJUNI - INACTIVATED

<table>
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<tr>
<th>Year</th>
<th>Total Reports</th>
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<tr>
<td>2015</td>
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Presenting signs (probable and possible)

- Erythema (1)
- Injection site reaction (1)
- Pain (1)

### 5.4 CLOPROSTENOL SODIUM

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<th>Year</th>
<th>Total Reports</th>
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<tr>
<td>2015</td>
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Presenting signs (probable and possible)

- Vaginal discharge (1)

### 5.5 CLOSTRIDIUM CHAUVOEII - WHOLE CELL CULTURE

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<th>Year</th>
<th>Total Reports</th>
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<tr>
<td>2015</td>
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</table>

Presenting signs (probable and possible)

- Erythema (1)
- Swelling (local) (1)

### 5.6 CLOSTRIDIUM NOVYI TYPE B - TOXIOD AND INACTIVATED CELLS

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<th>Year</th>
<th>Total Reports</th>
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<tr>
<td>2015</td>
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Presenting signs (probable and possible)

- Erythema (1)
- Swelling (local) (1)

### 5.7 CLOSTRIDIUM NOVYI TYPE B

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Presenting signs (probable and possible)

- Erythema (1)
- Swelling (local) (1)
5.8 CLOSTRIDIUM PERFRINGENS TYPE D - TOXOID

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Presenting signs (probable and possible)
Erythema (1)  Swelling (local) (1)

5.9 CLOSTRIDIUM SEPTICUM - TOXOID

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Presenting signs (probable and possible)
Erythema (2)  Swelling (local) (2)

5.10 CLOSTRIDIUM TETANI - TOXOID

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Presenting signs (probable and possible)
Erythema (1)  Swelling (local) (1)

5.11 CORYNEBACTERIUM PSEUDOTUBERCULOSIS - TOXOID

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Presenting signs (probable and possible)
Erythema (1)  Swelling (local) (1)

5.12 DIAZINON

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Presenting signs (probable and possible)
Epistaxis (2)  Nausea (1)  Unpleasant smell (1)
### 5.13 DIFLUBENZURON

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**Presenting signs (probable and possible)**
- Headache (1)
- Malaise (1)
- Nausea (1)

### 5.14 FIPRONIL

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**Presenting signs (probable and possible)**
- Headache (1)

### 5.15 IMIDACLOPRID

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**Presenting signs (probable and possible)**
- Allergy (1)
- Pain (2)
- Unpleasant smell (1)
- Erythema (1)
- Paraesthesia (1)
- Unpleasant taste (2)
- Irritation (eye) (1)
- Irritation (skin) (1)
- Pruritus (1)
- Oral (irritation) (1)
- Respiratory problems (1)

### 5.16 INDOXACARB

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**Presenting signs (probable and possible)**
- Apnoea (3)
- Hypersensitivity reaction (1)
- Burning sensation (3)
- Nausea (1)
### 5.17 METHYL LAURATE

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Presenting signs (probable and possible)
- Anaphylaxis (1)
- Erythema (1)
- Oedema (1)
- Unpleasant taste (1)

### 5.18 METHYL LINOLEATE

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Presenting signs (probable and possible)
- Anaphylaxis (1)
- Erythema (1)
- Oedema (1)
- Unpleasant taste (1)

### 5.19 METHYL MYRISTATE

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Presenting signs (probable and possible)
- Anaphylaxis (1)
- Erythema (1)
- Oedema (1)
- Unpleasant taste (1)

### 5.20 METHYL OLEATE

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Presenting signs (probable and possible)
- Anaphylaxis (1)
- Erythema (1)
- Oedema (1)
- Unpleasant taste (1)
### 5.21 METHYL PALMITATE

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</table>

Presenting signs (probable and possible)
- Anaphylaxis (1)
- Erythema (1)
- Oedema (1)
- Unpleasant taste (1)

### 5.22 METHYL PENTADECANOATE

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Presenting signs (probable and possible)
- Anaphylaxis (1)
- Erythema (1)
- Oedema (1)
- Unpleasant taste (1)

### 5.23 METHYL STEARATE

<table>
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Presenting signs (probable and possible)
- Anaphylaxis (1)
- Erythema (1)
- Oedema (1)
- Unpleasant taste (1)

### 5.24 MOXIDECTIN

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<td>2</td>
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Presenting signs (probable and possible)
- Allergy (1)
- Irritation (eye) (1)
- Oral (irritation) (1)
- Pain (2)
- Paraesthesia (1)
- Respiratory problems (1)
- Unpleasant taste (2)

### 5.25 N-METHYL-2-PYRROLIDONE

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Presenting signs (probable and possible)
- Headache (1)
- Malaise (1)
- Nausea (1)
### 5.26 PERMETHRIN

<table>
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</table>

Presenting signs (probable and possible)
Unpleasant smell (1)

### 5.27 SYNTHETIC ANALOGUE OF THE CANINE APPEASING PHEROMONE

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</table>

Presenting signs (probable and possible)
Anaphylaxis (1) Oedema (1)
Erythema (1) Unpleasant taste (1)

### 5.28 TETANUS = CLOSTRIDIUM TETANI

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Presenting signs (probable and possible)
Erythema (1) Swelling (local) (1)

### 5.29 TILMICOSIN

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<tr>
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Presenting signs (probable and possible)
Needle stick injury (1) Site reaction (swelling) (1)
6 VETERINARY – STANDARD

This chapter summarises classifications of APVMA assessments of adverse experience reports involving registered veterinary medicines which occurred during 2015.

There were 4064 adverse experience events reported, which occurred in 2015 involving registered veterinary medicines of which:

- 80 per cent involved animal safety
- 18 per cent involved lack of efficacy and
- 2 per cent involved human health issues

The information presented in the following section should be considered with regard to APVMA guidance on how to read this report available at Chapter 1.2

6.1 (S)-METHOPRENE

Canine

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Presenting signs (probable and possible)
Frothing at the mouth (1)

Feline

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<tbody>
<tr>
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Presenting signs (probable and possible)
Ataxia (1) Death (1) Listless (1)
Behavioural change (1) Foaming (3) Seizure (2)
Convulsions (1) Hypersalivation (4) Vomiting (2)

6.2 ABALONE POWDER

Canine

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<tr>
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Presenting signs (probable and possible)
Diarrhoea (4) Melaena (2) Pruritus (2)
### 6.3 ABAMECTIN

#### Bovine

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Presenting signs (probable and possible)
- Ataxia (2)
- Collapse (1)
- Recumbency (1)

#### Ovine

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Presenting signs (probable and possible)
- Death (4)
- Malaise (1)
- Spasm (2)
- Lethargy (2)
- Recumbency (1)
- Stiffness (1)

### 6.4 ACEPROMAZINE MALEATE

#### Canine

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Presenting signs (probable and possible)
- Bradycardia (1)
- Hypothermia (1)
- Respiratory problems (1)
- Hypotension (1)
- Recovery (prolonged) (1)
- Sedation (prolonged) (1)

#### Equine

<table>
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Presenting signs (probable and possible)
- Injection site reaction (1)
- Swelling (local) (1)
- Urticaria (1)
6.5 ACETYL GLUCOSAMINE

Canine

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Presenting signs (probable and possible)
- Bradycardia (1)
- Nasal discharge (1)
- Weakness (1)
- Collapse (1)
- Sneezing (1)

Equine

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Presenting signs (probable and possible)
- Coat discoloration (1)

AFOXOLANER

Afoxolaner was registered in December 2014. Known side effects include vomiting, dry/flaky skin, diarrhoea, lethargy, and lack of appetite. Very rare are more serious adverse reactions have occurred including seizure and/or pyrexia (raised body temperature; fever).

In 2015, 18 AERs reported neurological issues, these are a serious reaction to the product. While the frequency of all reactions was not sufficient to trigger regulatory action (<1:10,000), public concern and the severity of some reactions supported a label change.

The registrant engaged with the APVMA to implement a label change in June 2016.

“Afoxolaner is part of the isoxazoline family of chemicals. Adverse reactions to this family of chemicals are rarely observed but may include vomiting, diarrhoea, lethargy, inappetance, itching and very rarely, seizures. Most adverse reactions are self-limiting and of short duration. If you have any concerns, please speak to your veterinarian.”
# 6.6 AFOXOLANER

**Canine**

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<td>199</td>
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**Presenting signs (probable and possible)**

- Adipsia (2)
- Haematemesis (1)
- Rash (4)
- Aggression (1)
- Hives (3)
- Recumbency (1)
- Agitation (15)
- Hyperactivity (1)
- Red eyes (1)
- Alopecia (2)
- Hypersalivation (5)
- Restless (5)
- Anisocoria (1)
- Incoordination (1)
- Retching (2)
- Anorexia (29)
- Irritation (ear) (1)
- Seizure (6)
- Ataxia (5)
- Irritation (skin) (9)
- Self-trauma (4)
- Behavioural change (7)
- Lesions (1)
- Shaking (2)
- Blood in faeces (1)
- Lethargy (60)
- Stiffness (1)
- Collapse (4)
- Malaise (10)
- Swelling (local) (1)
- Constipation (1)
- Melaena (6)
- Tachycardia (1)
- Convulsions (1)
- Muscle twitching (3)
- Tremor (3)
- Dehydration (1)
- Nasal discharge (1)
- Urticaria (1)
- Depression (2)
- Oedema (1)
- Vocalisation (1)
- Diarrhoea (35)
- Panting (11)
- Vomiting (126)
- Disorientation (2)
- Periorbital swelling (1)
- Weakness (1)
- Distress (4)
- Polydipsia (5)
- Welts (2)
- Dyspnoea (1)
- Polyuria (3)
- Wheals (1)
- Erythema (23)
- Pruritus (71)
- Xerostomia (1)
- Facial oedema (1)
- Pyrexia (7)
### 6.7 AGLEPRISTONE

**Canine**

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Presenting signs (probable and possible)
- Ataxia (1)
- Pyrexia (1)
- Lack of effect (1)
- Vaginal discharge (1)

### 6.8 ALBENDAZOLE

**Ovine**

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Presenting signs (probable and possible)
- Death (2)
- Malaise (1)
- Lethargy (2)
- Stiffness (1)

### 6.9 ALPHAXALONE

**Canine**

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Presenting signs (probable and possible)
- Anaesthesia (deep) (1)
- Injected mucous membranes (2)
- Respiratory problems (2)
- Death (1)
- Nystagmus (2)
- Seizure (1)
- Erythema (1)
- Opisthotonos (1)
- Stiffness (1)
- Facial oedema (2)
- Paddling (4)
- Tremor (1)
- Hives (2)
- Periorbital swelling (2)
- Vocalisation (1)
- Vomiting (1)
### Feline

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</table>

Presenting signs (probable and possible)

- Apnoea (1)
- Death (1)
- Opisthotonos (1)
- Recovery (prolonged) (2)
- Respiratory problems (1)
- Stiffness (1)

### ALUMINIUM HYDROXIDE

### Canine

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Presenting signs (probable and possible)

- Allergy (1)
- Anaphylactoid reaction (1)
- Anaphylaxis (2)
- Anorexia (1)
- Apnoea (1)
- Bradycardia (1)
- Collapse (1)
- Diarrhoea (1)
- Facial oedema (6)
- Hyperaesthesia (1)
- Injection site reaction (10)
- Lethargy (4)
- Lump (local) (7)
- Masticatory myositis (1)
- Pain (2)
- Pale mucous membranes (1)
- Periorbital swelling (1)
- Pyrexia (1)

- Recumbency (1)
- Red eyes (1)
- Swelling (local) (1)
- Tremor (1)
- Urticaria (1)
- Vocalisation (1)
- Vomiting (4)

### Feline

<table>
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Presenting signs (probable and possible)

- Anorexia (1)
- Lethargy (1)
- Pyrexia (1)
## 6.11 AMITRAZ

### Bovine

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**Presenting signs (probable and possible)**
- Ataxia (1)
- Milk production decrease (1)
- Lethargy (1)
- Panting (1)
- Recumbency (1)
- Milk production decrease (1)
- Recumbency (1)

### Canine

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Reports</th>
<th>Total Probable</th>
<th>Total Possible</th>
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<tbody>
<tr>
<td>2015</td>
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<td>3</td>
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</table>

**Presenting signs (probable and possible)**
- Agitation (1)
- Lethargy (2)
- Lethargy (2)
- Lethargy (2)
- Restless (1)
- Restless (1)
- Restless (1)
- Tremor (1)
- Vomiting (1)

## 6.12 AMOXYCILLIN TRIHYDRATE

### Canine

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<tbody>
<tr>
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<td>3</td>
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</table>

**Presenting signs (probable and possible)**
- Injection site reaction (2)
- Paralysis (1)
- Paralysis (1)
- Lesions (1)
- Site reaction (1)
- Site reaction (1)
- Pain (2)
- Swelling (local) (1)
- Swelling (local) (1)
- Vomiting (2)

### Feline

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**Presenting signs (probable and possible)**
- Injection site reaction (2)
- Lesions (1)
- Lesions (1)
- Lesions (1)
- Swelling (local) (1)
- Swelling (local) (1)
6.13  AMPHOTERICIN B

Feline

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</table>

Presenting signs (probable and possible)
- Anorexia (1)
- Lethargy (1)

6.14  ATROPINE SULFATE

Canine

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<tbody>
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Presenting signs (probable and possible)
- Respiratory problems (1)

6.15  AZELAIC ACID

Feline

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<th>Total Probable</th>
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</table>

Presenting signs (probable and possible)
- Lethargy (1)
- Pruritus (1)
- Sneezing (1)

6.16  BACITRACIN ZINC

Canine

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Presenting signs (probable and possible)
- Vomiting (1)
6.17  BENZAEPHRIL HYDROCHLORIDE

Canine

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</table>

Presenting signs (probable and possible)
- Diarrhoea (2)
- Polydipsia (1)
- Vomiting (5)
- Haemorrhage (1)
- Poluria (1)
- Melaena (2)
- Seizure (2)

Feline

<table>
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<tr>
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</table>

Presenting signs (probable and possible)
- Abnormal Biochemistry (1)
- Dehydration (1)
- Weight loss (1)
- Ulceration (1)

6.18  BENZALKONIUM CHLORIDE

Canine

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</table>

Presenting signs (probable and possible)
- Erythema (1)
- Site reaction (1)
- Ulceration (1)

6.19  BETAMETHASONE VALERATE

Canine

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<tr>
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</table>

Presenting signs (probable and possible)
- Anorexia (1)
- Erythema (1)
- Malaise (1)
- Blisters (1)
- Irritation (eye) (1)
- Ulceration (1)
- Deafness (2)
- Lethargy (1)
### 6.20 BIOTA ORIENTALIS SEED OIL

#### Canine

<table>
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<tbody>
<tr>
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<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

**Presenting signs (probable and possible)**

- Diarrhoea (2)
- Melaena (1)

#### BORDETELLEA BRONCHISEPTICA VACCINES

*Bordetella bronchiseptica* is a component of ‘non-core’ canine vaccine products that target common canine respiratory illness. Non-core vaccines are required only for animals at risk from a specific disease due to their geographical location or local environment.

The most commonly reported presenting signs included coughing, lethargy and injection-site reaction (inactivated, cell-free vaccine), and facial oedema and vomiting (killed vaccine). These symptoms occur occasionally with vaccines. Vaccines act by stimulating an immune response, which protects the animal from serious illnesses. However, this immune response is also responsible for most of the presenting signs observed.

The APVMA notes that vaccines are often used in conjunction with other products (including other vaccines) which could also result in a higher number of reports. In most cases it is not possible to attribute the cause of an adverse reaction to a single active constituent or to a specific product used concurrently. Hence a single report may be classified against multiple active constituents that may have a potential causal relationship with an adverse experience.

To protect from serious illnesses, a very large number of pets are vaccinated every year. The number of reports associated with *Bordetella bronchiseptica* vaccine strains is below the action level of 1 reaction in 10,000 doses sold in 2015. At this time no regulatory action is required, however vaccine products are continually monitored for unexpected or severe reactions.
## 6.21 BORDETELLA BRONCHISEPTICA

### Canine

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<td>23</td>
<td>146</td>
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</tbody>
</table>

**Presenting signs (probable and possible)**

- Agitation (2)  
  - Haemorrhage (2)  
  - Pulmonary oedema (1)
- Allergy (2)  
  - Hives (1)  
  - Pyrexia (12)
- Alopecia (1)  
  - Hyperaesthesia (1)  
  - Rash (4)
- Anaphylactoid reaction (2)  
  - Hypersalivation (3)  
  - Recumbency (1)
- Anaphylaxis (9)  
  - Hypotension (2)  
  - Red eyes (2)
- Anorexia (10)  
  - Incontinence (2)  
  - Respiratory problems (5)
- Apnoea (1)  
  - Injection site reaction (38)  
  - Retching (1)
- Ataxia (1)  
  - Irritation (skin) (1)  
  - Seizure (1)
- Behavioural change (6)  
  - Lack of effect (3)  
  - Seroma (1)
- Blisters (1)  
  - Lame (1)  
  - Shaking (3)
- Bradycardia (2)  
  - Lethargy (25)  
  - Site reaction (2)
- Collapse (3)  
  - Lump (local) (29)  
  - Sneezing (22)
- Coughing (34)  
  - Malaise (4)  
  - Swelling (local) (6)
- Death (1)  
  - Masticatory myositis (1)  
  - Swelling (vulva) (1)
- Defaecation (1)  
  - Nasal discharge (8)  
  - Tachycardia (2)
- Dermatitis (1)  
  - Oedema (1)  
  - Tachypnoea (2)
- Diarrhoea (8)  
  - Pain (16)  
  - Thrombocytopenia (1)
- Dyspnoea (1)  
  - Pale mucous membranes (6)  
  - Tremor (2)
- Erythema (1)  
  - Panting (1)  
  - Urticaria (2)
- Facial oedema (23)  
  - Paraesthesia (1)  
  - Vocalisation (3)
- Frothing at the mouth (1)  
  - Periorbital swelling (7)  
  - Vomiting (32)
- Gagging (1)  
  - Polyarthrits (1)  
  - Weakness (1)
- Haematoma (1)  
  - Pruritus (3)
6.22  BORDETELLA BRONCHISEPTICA KILLED VACCINE

Canine

<table>
<thead>
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<td>43</td>
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</tbody>
</table>

Presenting signs (probable and possible)

- Anaphylaxis (8)
- Hypersalivation (1)
- Respiratory problems (1)
- Anorexia (2)
- Hypotension (1)
- Restless (1)
- Ataxia (1)
- Injection site reaction (4)
- Shaking (1)
- Bradycardia (1)
- Lethargy (3)
- Swelling (local) (1)
- Capillary refill time (slow) (2)
- Listless (1)
- Tachycardia (3)
- Circulatory collapse (1)
- Lump (local) (1)
- Tachypnoea (2)
- Collapse (4)
- Pain (3)
- Thrombocytopenia (1)
- Diarrhoea (3)
- Pale mucous membranes (2)
- Urticaria (6)
- Disorientation (1)
- Panting (1)
- Vocalisation (1)
- Facial oedema (15)
- Polydipsia (1)
- Vomiting (17)
- Haematemesis (2)
- Pruritus (5)
- Weakness (1)
- Hives (2)
- Pyrexia (4)

6.23  BOVINE CORONAVIRUS (CA-5)

Bovine

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>2015</td>
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<td>1</td>
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</tbody>
</table>

Presenting signs (probable and possible)

- Abscess (1)
- Stiffness (1)
### 6.24 BOVINE CORONAVIRUS (INACTIVATED)

**Bovine**

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<tr>
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<tbody>
<tr>
<td>2015</td>
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<td>1</td>
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</tbody>
</table>

**Presenting signs (probable and possible)**
- Abscess (1)  
- Stiffness (1)

### 6.25 BOVINE CORONAVIRUS (WI-17)

**Bovine**

<table>
<thead>
<tr>
<th>Year</th>
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<tbody>
<tr>
<td>2015</td>
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<td>1</td>
</tr>
</tbody>
</table>

**Presenting signs (probable and possible)**
- Abscess (1)  
- Stiffness (1)

### 6.26 BOVINE PESTIVIRUS - BEGA STRAIN - INACTIVATED

**Bovine**

<table>
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<tr>
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<td>2015</td>
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<td>1</td>
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</tbody>
</table>

**Presenting signs (probable and possible)**
- Anaphylactoid reaction (1)  
- Lethargy (1)  
- Anorexia (1)  
- Malaise (1)

### 6.27 BOVINE PESTIVIRUS - TRANGIE STRAIN - INACTIVATED

**Bovine**

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Reports</th>
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<tr>
<td>2015</td>
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<td>1</td>
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</tbody>
</table>

**Presenting signs (probable and possible)**
- Anaphylactoid reaction (1)  
- Lethargy (1)  
- Anorexia (1)  
- Malaise (1)
6.28  BOVINE ROTAVIRUS (04-1)

<table>
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Presenting signs (probable and possible)
Abscess (1)  Stiffness (1)

6.29  BOVINE ROTAVIRUS (NCDV)

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Presenting signs (probable and possible)
Abscess (1)  Stiffness (1)

6.30  BOVINE VIRAL DIARRHOEA VIRUS BEGA STRAIN

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<th>Total Probable</th>
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<td>0</td>
<td>1</td>
</tr>
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</table>

Presenting signs (probable and possible)
Anaphylactoid reaction (1)  Lethargy (1)
Anorexia (1)  Malaise (1)

6.31  BOVINE VIRAL DIARRHOEA VIRUS TRANGIE STRAIN

<table>
<thead>
<tr>
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<tbody>
<tr>
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</table>

Presenting signs (probable and possible)
Anaphylactoid reaction (1)  Lethargy (1)
Anorexia (1)  Malaise (1)
6.32 BUTORPHANOL TARTRATE

Canine

<table>
<thead>
<tr>
<th>Year</th>
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<tbody>
<tr>
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Presenting signs (probable and possible)
Death (2)

6.33 CAMPYLOBACTER FETUS (VIBRO FETUS)

Ovine

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Presenting signs (probable and possible)
Anorexia (1) Lethargy (1) Pain (1)

6.34 CAMPYLOBACTER JEJUNI SUB-SPECIES JEJUNI - INACTIVATED

Ovine

<table>
<thead>
<tr>
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<tr>
<td>2015</td>
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</table>

Presenting signs (probable and possible)
Anorexia (1) Lethargy (1) Pain (1)

CANINE ADENOVIRUS TYPE 2 VACCINES

Canine adenovirus type 2 is a constituent of ‘core’ canine vaccine products that target common canine systemic illness. Core vaccines protect animals from severe, life-threatening diseases with worldwide distribution.

The most commonly reported presenting signs included facial oedema, vomiting, lethargy, injection site reaction, allergic reactions and coughing. These symptoms occur occasionally with vaccines. Vaccines act by stimulating an immune response, which protects the animal from serious illnesses. However, this immune response is also responsible for most of the presenting signs observed.

The APVMA notes that vaccines are often used in conjunction with other products (including other vaccines) which could also result in a higher number of reports. In most cases it is not possible to attribute the cause of an adverse reaction to a single active constituent or to any of the products used concurrently. Hence a single report may be classified against multiple active constituents that may have a potential causal relationship with an adverse experience.
To protect from serious illnesses, a very large number of pets are vaccinated every year. The number of reports associated with canine adenovirus vaccine strains is low when compared with the number of doses sold in 2015 (less than 1 in 10000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

### 6.35 CANINE ADENOVIRUS TYPE 2

**Canine**

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<td>111</td>
</tr>
</tbody>
</table>

**Presenting signs (probable and possible)**

- Agitation (3)  
  - Haematoma (1)  
  - Pruritus (9)
- Alopecia (2)  
  - Hives (3)  
  - Pyrexia (14)
- Anaphylactoid reaction (1)  
  - Hypersalivation (3)  
  - Rash (2)
- Anaphylaxis (15)  
  - Hypotension (4)  
  - Respiratory problems (5)
- Anorexia (6)  
  - Incontinence (1)  
  - Restless (1)
- Apnoea (1)  
  - Injection site reaction (20)  
  - Seizure (1)
- Ataxia (3)  
  - Lame (1)  
  - Shaking (6)
- Behavioural change (3)  
  - Lethargy (17)  
  - Sneezing (17)
- Bradycardia (3)  
  - Listless (1)  
  - Stomatitis (1)
- Capillary refill time (slow) (2)  
  - Lump (local) (14)  
  - Swelling (local) (2)
- Circulatory collapse (1)  
  - Malaise (2)  
  - Swelling (vulva) (2)
- Collapse (7)  
  - Nasal discharge (4)  
  - Tachycardia (4)
- Coughing (27)  
  - Oedema (2)  
  - Tachypnoea (4)
- Deafness (1)  
  - Pain (14)  
  - Thrombocytopenia (1)
- Death (1)  
  - Pale mucous membranes (7)  
  - Tremor (1)
- Depression (1)  
  - Panting (2)  
  - Urticaria (8)
- Diarrhoea (6)  
  - Paraesthesia (1)  
  - Vocalisation (2)
- Disorientation (1)  
  - Periorbital swelling (3)  
  - Vomiting (37)
- Facial oedema (27)  
  - Polyarthritis (1)  
  - Weakness (3)
- Haematemesis (2)  
  - Polydipsia (1)
### 6.36 CANINE ADENOVIRUS TYPE 2 - LIVE (INFECTIOUS HEPATITIS)

<table>
<thead>
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<td>29</td>
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</table>

**Presenting signs (probable and possible)**

- Allergy (1)
- Hyperaesthesia (1)
- Recumbency (1)
- Anaphylactoid reaction (1)
- Injection site reaction (8)
- Red eyes (1)
- Anaphylaxis (4)
- Lethargy (5)
- Swelling (local) (1)
- Anorexia (1)
- Lump (local) (5)
- Tremor (1)
- Apnoea (1)
- Masticatory myositis (1)
- Vocalisation (1)
- Bradycardia (1)
- Pain (2)
- Vomiting (5)
- Collapse (1)
- Pale mucous membranes (1)
- Welts (1)
- Erythema (1)
- Periorbital swelling (1)
- Facial oedema (11)
- Pyrexia (1)

### 6.37 CANINE ADENOVIRUS TYPE 2 - LIVE (CAV II)

<table>
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</table>

**Presenting signs (probable and possible)**

- Anorexia (1)
- Facial oedema (4)
- Pyrexia (2)
- Bradycardia (1)
- Haematemesis (1)
- Rash (1)
- Capillary refill time (slow) (1)
- Hives (1)
- Sneezing (1)
- Collapse (1)
- Lethargy (1)
- Tachycardia (1)
- Coughing (2)
- Pain (1)
- Tachypnoea (1)
- Depression (1)
- Pale mucous membranes (2)
- Urticaria (1)
- Diarrhoea (1)
- Pruritus (1)
- Vomiting (6)
### 6.38 CANINE ADENOVIRUS TYPE 2 STRAIN MANHATTAN - LIVE

#### Canine

<table>
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<tr>
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<td>32</td>
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</table>

#### Presenting signs (probable and possible)

- Allergy (1)
- Haemorrhage (1)
- Pruritus (2)
- Anaphylaxis (3)
- Hives (1)
- Pulmonary oedema (1)
- Anorexia (3)
- Hypersalivation (2)
- Pyrexia (3)
- Ataxia (1)
- Incontinence (1)
- Rash (3)
- Behavioural change (3)
- Injection site reaction (2)
- Red eyes (1)
- Blisters (1)
- Irritation (skin) (1)
- Respiratory problems (1)
- Death (2)
- Lethargy (6)
- Site reaction (1)
- Defaecation (1)
- Lump (local) (3)
- Swelling (local) (1)
- Dermatitis (1)
- Nasal discharge (2)
- Tachycardia (1)
- Diarrhoea (4)
- Pain (3)
- Urticaria (1)
- Dyspnoea (1)
- Pale mucous membranes (2)
- Vomiting (12)
- Facial oedema (9)
- Periorbital swelling (4)

### 6.39 CANINE CORONAVIRUS VACCINE - ANTIGEN

#### Canine

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#### Presenting signs (probable and possible)

- Anaphylaxis (1)
- Injection site reaction (1)
- Rash (1)
- Facial oedema (1)
- Lump (local) (1)
- Swelling (vulva) (1)
- Hives (1)
- Periorbital swelling (1)
- Vomiting (2)
CANINE DISTEMPER VACCINES

Canine Distemper is a constituent of ‘core’ canine vaccine products that target common canine systemic illness. Core vaccines protect animals from severe, life-threatening diseases with worldwide distribution.

The most commonly reported presenting sign is lack of effect. This vaccine is given with Canine Parvovirus, most commonly the issue relates to poor seroconversion of high challenge relating to the Parvovirus component. This is a known issue and if you are concerned, it is best to discuss this with your veterinarian. Other presenting signs include facial oedema, vomiting, lethargy, injection site reaction, allergic reaction and coughing. These symptoms occur occasionally with vaccines of this type. Vaccines act by stimulating an immune response, which protects the animal from serious illnesses. However, this immune response is also responsible for most of the presenting signs observed.

The APVMA notes that vaccines are often used in conjunction with other products (including other vaccines) which could also result in a higher number of reports. In most cases it is not possible to attribute the cause of an adverse reaction to a single active constituent or to any of the products used concurrently. Hence a single report may be classified against multiple active constituents that may have a potential causal relationship with an adverse experience.

To protect from serious illnesses, a very large number of pets are vaccinated every year. The number of reports associated with canine distemper vaccine strains is low when compared with the number of doses sold in 2015 (less than 1 in 10000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.
## 6.40 CANINE DISTEMPER VIRUS

### Canine

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<td>128</td>
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### Presenting signs (probable and possible)
- Agitation (4)  Haematoma (2)  Pruritus (9)
- Allergy (1)    Hives (4)      Pyrexia (14)
- Alopecia (1)   Hyperaesthesia (1)  Rash (2)
- Anaphylactoid reaction (2)  Hypersalivation (2)  Recumbency (1)
- Anaphylaxis (17)  Hypotension (3)  Red eyes (1)
- Anorexia (7)    Incontinence (1)  Respiratory problems (2)
- Apnoea (2)      Injection site reaction (29)  Restless (1)
- Ataxia (3)      Lame (2)     Seizure (1)
- Behavioural change (2)  Lethargy (21)  Shaking (6)
- Bradycardia (4)  Listless (1)  Sneezeing (6)
- Capillary refill time (slow) (3)  Lump (local) (20)  Stomatitis (1)
- Circulatory collapse (1)  Malaise (2)  Swelling (local) (3)
- Collapse (9)   Masticatory myositis (1)  Swelling (vulva) (1)
- Coughing (11)  Nasal discharge (1)  Tachycardia (5)
- Deafness (1)   Oedema (2)       Tachypnoea (5)
- Death (1)      Pain (17)     Thrombocytopenia (1)
- Depression (2) Pale mucous membranes (8)  Tremor (1)
- Diarrhoea (7)  Panting (2)    Urticaria (9)
- Disorientation (1)  Paraesthesia (1)  Vocalisation (3)
- Erythema (1)    Periorbital swelling (2)  Vomiting (45)
- Facial oedema (40)  Polyarthritis (1)  Weakness (2)
- Haematemesisis (3)  Polydipsia (1)  Welts (1)
6.41 CANINE DISTEMPER VIRUS STRAIN ONDERSTEPOORT

### Canine

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#### Presenting signs (probable and possible)

- Allergy (1)
- Anaphylaxis (3)
- Anorexia (3)
- Ataxia (1)
- Behavioural change (3)
- Blisters (1)
- Death (2)
- Defaecation (1)
- Dermatitis (1)
- Diarrhoea (4)
- Dyspnoea (1)
- Facial oedema (9)
- Haemorrhage (1)
- Hives (1)
- Hypersalivation (2)
- Incontinence (1)
- Injection site reaction (2)
- Irritation (skin) (1)
- Lethargy (6)
- Lump (local) (3)
- Nasal discharge (2)
- Pain (3)
- Pale mucous membranes (2)
- Periorbital swelling (4)
- Pruritus (2)
- Pulmonary oedema (1)
- Pyrexia (3)
- Rash (3)
- Red eyes (1)
- Respiratory problems (1)
- Site reaction (1)
- Swelling (local) (1)
- Tachycardia (1)
- Urticaria (1)
- Vomiting (12)

### CANINE PARAINFLUENZA VACCINES

Canine parainfluenza virus and associated strains is a component of ‘non-core’ canine vaccine products that target common canine respiratory illnesses. Non-core vaccines are required only for those animals at risk from specific diseases due to their geographical location or local environment.

The most commonly reported presenting signs included injection site reaction, facial oedema, lethargy and coughing. These symptoms occur occasionally with vaccines of this type. Vaccines act by stimulating an immune response, which protects the animal from serious illnesses. However, this immune response is also responsible for most of the presenting signs observed.

The APVMA notes that vaccines are often used in conjunction with other products (including other vaccines) which could also result in a higher number of reports. In most cases it is not possible to attribute the cause of an adverse reaction to a single active constituent or to any of the products used concurrently. Hence a single report may be classified against multiple active constituents that may have a potential causal relationship with an adverse experience.
The number of reports associated with Canine parainfluenza virus vaccine strains is below the action level of 1 reaction in 10,000 doses sold in 2015. At this time no regulatory action is required, however vaccine products are continually monitored for unexpected or severe reactions.

### 6.42 CANINE PARAINFLUENZA TYPE 2

#### Canine

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#### Presenting signs (probable and possible)

- Agitation (2)
- Haematemesis (2)
- Pyrexia (4)
- Anaphylactoid reaction (1)
- Hives (2)
- Respiratory problems (1)
- Anaphylaxis (11)
- Hypersalivation (1)
- Restless (1)
- Anorexia (2)
- Hypotension (2)
- Shaking (1)
- Ataxia (1)
- Incontinence (1)
- Sneezing (1)
- Bradycardia (2)
- Injection site reaction (4)
- Swelling (local) (1)
- Capillary refill time (slow) (2)
- Lethargy (8)
- Tachycardia (4)
- Circulatory collapse (1)
- Listless (1)
- Tachypnoea (4)
- Collapse (6)
- Lump (local) (1)
- Thrombocytopenia (1)
- Coughing (1)
- Pain (5)
- Urticaria (7)
- Deafness (1)
- Pale mucous membranes (4)
- Vocalisation (1)
- Depression (1)
- Panting (2)
- Vomiting (22)
- Diarrhoea (4)
- Paraesthesia (1)
- Weakness (1)
- Disorientation (1)
- Polydipsia (1)
- Facial oedema (19)
- Pruritus (7)
6.43 CANINE PARAINFLUENZA VIRUS

Canine

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Presenting signs (probable and possible)

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<td>Facial oedema (30)</td>
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<td>Alopecia (1)</td>
<td>Frothing at the mouth (1)</td>
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<td>Anaphylactoid reaction (2)</td>
<td>Gagging (1)</td>
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<td>Anorexia (13)</td>
<td>Haematoma (1)</td>
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<td>Haemorrhage (2)</td>
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<td>Behavioural change (7)</td>
<td>Hives (2)</td>
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<tr>
<td>Blisters (1)</td>
<td>Hypersalivation (4)</td>
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<td>Listless (1)</td>
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VETERINARY - STANDARD

Swelling (vulva) (1)  Thrombocytopenia (2)  Vocalisation (3)
Tachycardia (4)      Tremor (1)          Vomiting (44)
Tachypnoea (3)       Urticaria (7)       Weakness (2)

6.44 CANINE PARAINFLUENZA VIRUS - INACTIVATED

Canine

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Presenting signs (probable and possible)

- Allergy (1)
- Hyperaesthesia (1)
- Recumbency (1)
- Anaphylactoid reaction (1)
- Injection site reaction (10)
- Red eyes (1)
- Anaphylaxis (2)
- Lethargy (4)
- Swelling (local) (1)
- Anorexia (1)
- Lump (local) (7)
- Tremor (1)
- Apnoea (1)
- Masticatory myositis (1)
- Urticaria (1)
- Bradycardia (1)
- Pain (2)
- Vocalisation (1)
- Collapse (1)
- Pale mucous membranes (1)
- Vomiting (4)
- Diarrhoea (1)
- Periorbital swelling (1)
- Facial oedema (6)
- Pyrexia (1)

CANINE PARVO VIRUS VACCINES

Canine parvovirus strains area constituent of ‘core’ canine vaccine products that target common canine systemic illness. Core vaccines protect animals from severe, life-threatening diseases with worldwide distribution.

The most commonly reported presenting signs included lack of effect, anaphylactoid reaction, facial oedema, vomiting, injection site reaction and lethargy. These symptoms occur occasionally with vaccines of this type. Vaccines act by stimulating an immune response, which protects the animal from serious illnesses. However, this immune response is also responsible for most of the presenting signs observed.

The most commonly reported presenting sign is Lack of effect. This commonly relates to poor seroconversion or high challenge of parvovirus. This is a known issue and if you are concerned, it is best to discuss this with your veterinarian.

The APVMA notes that vaccines are often used in conjunction with other products (including other vaccines) which could also result in a higher number of reports. In most cases it is not possible to attribute the cause of an adverse reaction to a single active constituent or to any of the products used concurrently.
Hence a single report may be classified against multiple active constituents that may have a potential causal relationship with an adverse experience.

The number of reports associated with canine parvovirus vaccine strains is below the action level of 1 reaction in 10,000 doses sold in 2015. At this time no regulatory action is required, however vaccine products are continually monitored for unexpected or severe reactions.

## 6.45 CANINE PARVO VIRUS

### Canine

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### Presenting signs (probable and possible)

- Agitation (3)
- Alopecia (1)
- Anaphylactoid reaction (1)
- Anaphylaxis (13)
- Anorexia (4)
- Apnoea (1)
- Ataxia (3)
- Behavioural change (2)
- Bradycardia (2)
- Capillary refill time (slow) (2)
- Circulatory collapse (1)
- Collapse (7)
- Coughing (9)
- Deafness (1)
- Death (1)
- Depression (1)
- Diarrhoea (6)
- Disorientation (1)
- Facial oedema (24)

- Haematemesis (2)
- Haematoma (1)
- Hives (3)
- Hypersalivation (2)
- Hypotension (3)
- Incontinence (1)
- Injection site reaction (15)
- Lame (1)
- Lethargy (12)
- Listless (1)
- Lump (local) (14)
- Nasal discharge (1)
- Oedema (2)
- Pain (9)
- Pale mucous membranes (5)
- Panting (2)
- Paraesthesia (1)
- Periorbital swelling (1)
- Polyarthritis (1)

- Polydipsia (1)
- Pruritus (8)
- Pyrexia (9)
- Rash (1)
- Respiratory problems (2)
- Restless (1)
- Seizure (1)
- Shaking (4)
- Sneezing (5)
- Stomatitis (1)
- Swelling (local) (1)
- Swelling (vulva) (1)
- Tachycardia (4)
- Tachypnoea (4)
- Thrombocytopenia (1)
- Urticaria (7)
- Vocalisation (2)
- Vomiting (31)
- Weakness (2)
### 6.46 CANINE PARVO VIRUS 2B STRAIN CPV39 - ATTENUATED

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**Presenting signs (probable and possible)**

- Anorexia (1)
- Facial oedema (4)
- Pyrexia (2)
- Bradycardia (1)
- Haematemesis (1)
- Rash (1)
- Capillary refill time (slow) (1)
- Hives (1)
- Sneezing (1)
- Collapse (1)
- Lethargy (1)
- Tachycardia (1)
- Coughing (2)
- Pain (1)
- Tachypnoea (1)
- Depression (1)
- Pale mucous membranes (2)
- Urticaria (1)
- Diarrhoea (1)
- Pruritus (1)
- Vomiting (6)

### 6.47 CANINE PARVO VIRUS TYPE 2

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**Presenting signs (probable and possible)**

- Anorexia (1)
- Malaise (2)
- Swelling (local) (1)
- Facial oedema (1)
- Pain (5)
- Urticaria (1)
- Injection site reaction (5)
- Pyrexia (2)
- Vomiting (1)
- Lethargy (3)
- Shaking (1)

### 6.48 CANINE PARVO VIRUS - INACTIVATED

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**Presenting signs (probable and possible)**

- Facial oedema (1)
- Urticaria (1)
6.49 CANINE PARVO VIRUS - LIVE

**Canine**

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</table>

**Presenting signs (probable and possible)**

- Agitation (1)  
  - Haematoma (1)  
  - Pyrexia (1)  
- Allergy (1)  
  - Hyperaesthesia (1)  
  - Recumbency (1)  
- Anaphylactoid reaction (1)  
  - Injection site reaction (9)  
  - Red eyes (1)  
- Anaphylaxis (4)  
  - Lame (1)  
  - Shaking (1)  
- Anorexia (1)  
  - Lethargy (5)  
  - Swelling (local) (1)  
- Apnoea (1)  
  - Lump (local) (6)  
  - Tremor (1)  
- Bradycardia (1)  
  - Masticatory myositis (1)  
  - Vocalisation (1)  
- Collapse (1)  
  - Pain (2)  
  - Vomiting (7)  
- Erythema (1)  
  - Pale mucous membranes (1)  
  - Welts (1)  
- Facial oedema (11)  
  - Periorbital swelling (1)  

6.50 CANINE PARVO VIRUS STRAIN 154 - LIVE

**Canine**

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<td>32</td>
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</table>

**Presenting signs (probable and possible)**

- Allergy (1)  
  - Defaecation (1)  
  - Hypersalivation (2)  
- Anaphylaxis (3)  
  - Dermatitis (1)  
  - Incontinence (1)  
- Anorexia (3)  
  - Diarrhoea (4)  
  - Injection site reaction (2)  
- Ataxia (1)  
  - Dyspnoea (1)  
  - Irritation (skin) (1)  
- Behavioural change (3)  
  - Facial oedema (9)  
  - Lethargy (6)  
- Blisters (1)  
  - Haemorrhage (1)  
  - Lump (local) (3)  
- Death (2)  
  - Hives (1)  
  - Nasal discharge (2)
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### Presenting signs (probable and possible)

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<th>Anaemia (1)</th>
<th>Behavioural change (1)</th>
<th>Lame (1)</th>
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<tbody>
<tr>
<td>Ataxia (2)</td>
<td>Dyspnoea (1)</td>
<td>Tachycardia (1)</td>
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</table>

### 6.52 CARPROFEN

### Canine

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### Presenting signs (probable and possible)

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<th>Abscess (1)</th>
<th>Anorexia (1)</th>
<th>Lethargy (1)</th>
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<tbody>
<tr>
<td>Anaphylactoid reaction (1)</td>
<td>Facial oedema (1)</td>
<td>Pruritus (1)</td>
</tr>
<tr>
<td>Anaphylaxis (1)</td>
<td>Injection site reaction (1)</td>
<td>Urticaria (1)</td>
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### Feline

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### Presenting signs (probable and possible)

<table>
<thead>
<tr>
<th>Alopecia (localised) (1)</th>
<th>Injection site reaction (1)</th>
<th>Ulceration (1)</th>
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### 6.53 Cefovecin Sodium

**Canine**

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Presenting signs (probable and possible)

- Vomiting (2)

**Feline**

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</tbody>
</table>

Presenting signs (probable and possible)

- Alopecia (localised) (2)
- Injection site reaction (2)
- Ulceration (2)

### 6.54 Cephalexin Monohydrate

**Canine**

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Presenting signs (probable and possible)

- Agitation (2)
- Lump (local) (2)
- Injection site reaction (2)
- Pain (2)

**Feline**

<table>
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Presenting signs (probable and possible)

- Diarrhoea (2)
- Lethargy (2)
- Vomiting (4)
6.55 CETRIMIDE

Canine

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</table>

Presenting signs (probable and possible)

- Erythema (1)
- Site reaction (1)
- Ulceration (1)

6.56 CHLAMYDOPHILIA FELIS INACTIVATED

Feline

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</table>

Presenting signs (probable and possible)

- Alopecia (localised) (3)
- Erythema (1)
- Oedema (2)
- Anorexia (2)
- Facial oedema (3)
- Pain (1)
- Cellulitis (1)
- Injection site reaction (6)
- Pruritus (2)
- Death (1)
- Lethargy (6)
- Pyrexia (5)
- Diarrhoea (1)
- Lump (local) (1)
- Site reaction (1)
- Distress (1)
- Nausea (1)
- Vomiting (3)

6.57 CHLORAMPHENICOL

Canine

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Presenting signs (probable and possible)

- Sneezing (1)
### 6.58 CHLORFENVINPHOS

**Bovine**

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</table>

**Presenting signs (probable and possible)**

- Ataxia (1)
- Panting (1)
- Lethargy (1)
- Recumbency (1)

### 6.59 CHLORHEXIDINE GLUCONATE

**Canine**

<table>
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</table>

**Presenting signs (probable and possible)**

- Erythema (2)
- Irritation (skin) (2)
- Pruritus (2)
- Gagging (1)
- Malaise (2)
- Retching (1)
- Irritation (paws) (2)
- Pododermatitis (2)

### 6.60 CHLORPHENIRAMINE MALEATE

**Canine**

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<tr>
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</table>

**Presenting signs (probable and possible)**

- Lethargy (1)
- Malaise (1)
- Vomiting (2)
6.61 CLAVULANIC ACID AS POTASSIUM CLAVULANATE

Canine

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<thead>
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Presenting signs (probable and possible)
- Injection site reaction (2)
- Paralysis (1)
- Vomiting (1)
- Lesions (1)
- Site reaction (1)
- Pain (2)
- Swelling (local) (1)

Feline

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<th>Total Possible</th>
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</table>

Presenting signs (probable and possible)
- Injection site reaction (2)
- Lesions (1)
- Swelling (local) (1)

6.62 CLOMIPRAMINE HYDROCHLORIDE

Canine

<table>
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<tr>
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<tbody>
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</table>

Presenting signs (probable and possible)
- Anorexia (1)
- Elevated ALP (1)
- Pain (1)
- Behavioural change (1)
- Elevated ALT (1)
- Pruritus (2)
- Diarrhoea (1)
- Listless (1)
- Vomiting (5)

Feline

<table>
<thead>
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Presenting signs (probable and possible)
- Constipation (1)
- Urinary retention (2)
6.63  CLOSTRIDIUM PERFRINGENS TYPE C - TOXOID

Bovine

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Presenting signs (probable and possible)
Abscess (1)  Stiffness (1)

6.64  CLOSTRIDIUM PERFRINGENS TYPE D - TOXOID

Bovine

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Presenting signs (probable and possible)
Abscess (1)  Stiffness (1)

Ovine

<table>
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<th>Year</th>
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<th>Total Possible</th>
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Presenting signs (probable and possible)
Injection site reaction (1)  Lame (1)  Lump (local) (1)

6.65  CLOSTRIDIUM TETANI - TOXOID

Ovine

<table>
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Presenting signs (probable and possible)
Injection site reaction (1)  Lame (1)  Lump (local) (1)
6.66 CLOSTRIDIUM TETANI UF TOXOID

Equine

<table>
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<tr>
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<td>13</td>
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Presenting signs (probable and possible)

- Allergy (1)
- Anorexia (2)
- Ataxia (1)
- Coat colour change (1)
- Colic (1)
- Death (1)
- Diarrhoea (1)
- Inflammation (1)
- Injection site reaction (17)
- Laryngeal constriction (1)
- Lethargy (9)
- Lump (local) (1)
- Oedema (11)
- Pain (4)
- Pyrexia (2)
- Stiffness (5)
- Sweating (1)
- Swelling (local) (4)
- Urticaria (1)
- Walking (difficult) (1)

6.67 CLOTRIMAZOLE

Canine

<table>
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<tr>
<th>Year</th>
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<th>Total Possible</th>
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<tbody>
<tr>
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</table>

Presenting signs (probable and possible)

- Anorexia (1)
- Blisters (1)
- Deafness (3)
- Erythema (1)
- Irritation (ear) (1)
- Irritation (eye) (1)
- Lethargy (1)
- Malaise (1)
- Ulceration (1)

6.68 COBALT AS COBALT EDTA

Bovine

<table>
<thead>
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<th>Total Reports</th>
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<th>Total Possible</th>
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Presenting signs (probable and possible)

- Ataxia (1)
- Collapse (1)
### Ovine

<table>
<thead>
<tr>
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<tr>
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</table>

**Presenting signs (probable and possible)**
- Death (4)
- Malaise (1)
- Spasm (2)
- Lethargy (2)
- Recumbency (1)
- Stiffness (1)

#### 6.69 COBALT OXIDE

**Bovine**

<table>
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<tr>
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</tbody>
</table>

**Presenting signs (probable and possible)**
- Anorexia (1)
- Hypersalivation (1)
- Lethargy (1)

#### 6.70 COPPER AS COPPER DISODIUM EDTA

**Bovine**

<table>
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<tr>
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**Presenting signs (probable and possible)**
- Injection site reaction (1)
- Site reaction (swelling) (1)

#### 6.71 COPPER OXIDE (I AND II)

**Bovine**

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</tbody>
</table>

**Presenting signs (probable and possible)**
- Anorexia (1)
- Hypersalivation (1)
- Lethargy (1)
### 6.72 CORONAVIRUS

**Canine**

<table>
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**Presenting signs (probable and possible)**

- Agitation (1)
- Haematoma (1)
- Injection site reaction (1)
- Lame (1)
- Lump (local) (1)
- Shaking (1)
- Vomiting (2)

### 6.73 CORYNEBACTERIUM PSEUDOTUBERCULOSIS - TOXOID

**Ovine**

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**Presenting signs (probable and possible)**

- Injection site reaction (1)
- Lame (1)
- Lump (local) (1)

### 6.74 CORYNEBACTERIUM PSEUDOTUBERCULOSIS (OVIS) - TOXOID

**Ovine**

<table>
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</table>

**Presenting signs (probable and possible)**

- Injection site reaction (1)
- Lame (1)
- Lump (local) (1)

### 6.75 CUPRIC OXIDE

**Bovine**

<table>
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</table>

**Presenting signs (probable and possible)**

- Anorexia (1)
- Hypersalivation (1)
- Lethargy (1)
CYCLOSPORIN

Cyclosporin is a widely used immunosuppressant drug used in the treatment of immune-mediated conditions. The most commonly reported presenting signs are gastrointestinal related, most notably vomiting and diarrhoea.

The number of reports associated with Cyclosporin is low when compared with the number of doses sold in 2015 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

### 6.76 CYCLOSPORIN

#### Canine

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**Presenting signs (probable and possible)**

- Anorexia (3)  
- Ataxia (2)  
- Behavioural change (1)  
- Collapse (1)  
- Constipation (1)  
- Dermatitis (1)  
- Diabetes (2)  
- Diarrhoea (5)  
- Erythema (2)  
- Facial oedema (1)  
- Gingival hyperplasia (1)  
- Gingival soreness (1)  
- Hives (1)

- Horner's Syndrome (1)  
- Hyperactivity (1)  
- Illness (1)  
- Incontinence (2)  
- Insomnia (1)  
- Lack of effect (1)  
- Lame (1)  
- Lesions (2)  
- Lethargy (3)  
- Leukopenia (1)  
- Malaise (1)  
- Malaena (1)  
- Nausea (1)

- Pancreatitis (1)  
- Panting (1)  
- Papules (1)  
- Polydipsia (1)  
- Polyuria (1)  
- Pruritus (4)  
- Pyoderma (1)  
- Retching (1)  
- Tremor (3)  
- Unconscious (1)  
- Vocalisation (1)  
- Vomiting (21)  
- Weakness (2)
### Feline

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**Presenting signs (probable and possible)**
- Alopecia (1)
- Anorexia (1)
- Coat discoloration (1)
- Diarrhoea (3)
- Epiphora (1)
- Frothing at the mouth (1)
- Hypersalivation (1)
- Polyphagia (1)
- Vomiting (2)

### Canine

<table>
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</tr>
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**Presenting signs (probable and possible)**
- Behavioural change (1)

### Feline

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**Presenting signs (probable and possible)**
- Alopecia (1)
- Anorexia (1)
- Coat discoloration (1)
- Diarrhoea (3)
- Epiphora (1)
- Frothing at the mouth (1)
- Hypersalivation (1)
- Polyphagia (1)
- Vomiting (2)

### Ovine

<table>
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<tr>
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<th>Total Possible</th>
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<tbody>
<tr>
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**Presenting signs (probable and possible)**
- Low efficacy (1)
6.79 D.A.P BULK SOLUTION

Canine

<table>
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Presenting signs (probable and possible)

- Agitation (1)
- Alopecia (2)
- Dermatitis (1)
- Erythema (5)
- Facial oedema (1)
- Lesions (3)
- Pruritus (3)
- Rash (1)
- Site reaction (3)

DELTAMETHRIN

In 2012 a new product range was introduced to the market. It had a very high sales volume and a high number of reports related to canines were made. Reports peaked in 2014 and in 2015 decreased dramatically, to below 1 report in 10,000 units sold. The reactions recorded describe reactions at the application site, including localised skin lesions lesion, dermatitis or erythema, pruritus and alopecia. These are mentioned on the label and the rapidly improve when exposure is stopped.

6.80 DELTAMETHRIN

Canine

<table>
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<th>Year</th>
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<tr>
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Presenting signs (probable and possible)

- Agitation (3)
- Alopecia (1)
- Alopecia (localised) (2)
- Ataxia (1)
- Behavioural change (5)
- Collapse (1)
- Dermatitis (1)
- Erythema (5)
- Hyperactivity (1)
- Lame (1)
- Lesions (2)
- Lethargy (3)
- Pruritus (7)
- Restless (2)
- Site reaction (swelling) (1)
- Spasm (1)
- Vocalisation (1)
6.81 DESLORELIN ACETATE

Canine

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Presenting signs (probable and possible)
- Injection site reaction (2)
- Low efficacy (4)
- Site reaction (swelling) (2)

6.82 DETOMIDINE HYDROCHLORIDE

Equine

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Presenting signs (probable and possible)
- Urticaria (1)

6.83 DEXAMETHASONE PHENYLPROPIONATE

Canine

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Presenting signs (probable and possible)
- Anaphylaxis (1)
- Elevated ALT (1)
- Malaise (1)
- Anorexia (1)
- Lethargy (1)

6.84 DEXAMETHASONE SODIUM PHOSPHATE

Canine

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</table>

Presenting signs (probable and possible)
- Anaphylaxis (1)
- Elevated ALT (1)
- Malaise (1)
- Anorexia (1)
- Lethargy (1)
### 6.85 DEXTROMETHORPHAN HYDROBROMIDE

**Canine**

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Presenting signs (probable and possible)
- Lethargy (1)
- Malaise (1)

### 6.86 DIAZEPAM

**Feline**

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Presenting signs (probable and possible)
- Ataxia (1)
- Tachycardia (1)
- Vomiting (1)
- Site reaction (1)
- Tremor (1)

### 6.87 DIAZINON

**Bovine**

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Presenting signs (probable and possible)
- Death (1)
- Foaming (1)

### 6.88 DICHLOROPHEN

**Feline**

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Presenting signs (probable and possible)
- Ataxia (1)
- Shaking (1)
### 6.89 DICYCLANIL

**Ovine**

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**Presenting signs (probable and possible)**

Low efficacy (1)

### 6.90 DIFLUBENZURON

**Ovine**

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**Presenting signs (probable and possible)**

Lame (1)

### 6.91 DISODIUM EDETATE

**Ovine**

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**Presenting signs (probable and possible)**

Death (1)  
Lethargy (1)  
Stiffness (1)

### 6.92 DISODIUM MANGANONS ETHYLENE DIAMINE TETRAACETATE

**Ovine**

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**Presenting signs (probable and possible)**

Injection site reaction (2)  
Lame (1)  
Lump (local) (2)
### 6.93 DISODIUM TILUDRONATE

**Equine**

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Presenting signs (probable and possible)
- Anorexia (1)
- Polydipsia (1)

### 6.94 DL-ALPHA-TOCOPHERYL ACETATE

**Porcine**

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Presenting signs (probable and possible)
- Anorexia (1)
- Lethargy (1)
- Seizure (1)
- Death (1)
- Pyrexia (1)
- Site reaction (swelling) (1)
- Injection site reaction (1)
- Recumbency (1)
- Vomiting (1)

### 6.95 DORAMECTIN

**Canine**

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Presenting signs (probable and possible)
- Collapse (1)
- Vomiting (1)

### 6.96 DOXYCYCLINE MONOHYDRATE

**Feline**

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</table>

Presenting signs (probable and possible)
- Anorexia (2)
- Renal failure (2)
- Anuria (2)
- Vomiting (2)
6.97  EMODEPSIDE

Feline

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Presenting signs (probable and possible)
- Alopecia (7)
- Lethargy (1)
- Site reaction (5)
- Alopecia (localised) (1)
- Listless (1)
- Anorexia (2)
- Pruritus (1)

6.98  ENROFLOXACIN

Feline

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Presenting signs (probable and possible)
- Hypersalivation (1)
- Vomiting (1)

6.99  EPHEDRINE HYDROCHLORIDE

Canine

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Presenting signs (probable and possible)
- Lethargy (1)
- Malaise (1)

6.100  EQUINE HERPES VIRUS 1 (EHV-1) 438/77 STRAIN

Equine

<table>
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<th>Year</th>
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Presenting signs (probable and possible)
- Lethargy (1)
- Pyrexia (1)
6.101 EQUINE HERPES VIRUS 4 (EHV-4) 405/76 STRAIN

<table>
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Presenting signs (probable and possible)
Lethargy (1) Pyrexia (1)

6.102 ESCHERICHIA COLI K99 PILUS ANTIGENS

<table>
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Presenting signs (probable and possible)
Abscess (1) Stiffness (1)

FEBANTEL

Febantel is a broad-spectrum antiparasitic active ingredient used in veterinary medicine in pets and livestock against internal parasites (roundworms, tapeworms). The most common presenting sign was vomiting and the frequency of reactions is extremely rare, at a frequency well below 1 in 100,000.

6.103 FEBANTEL

<table>
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Presenting signs (probable and possible)
Agitation (1) Erythema (1) Injection site reaction (1)
Anaphylaxis (1) Facial oedema (1) Lethargy (7)
Anorexia (1) Hyperactivity (4) Low efficacy (2)
Collapse (3) Hypersalivation (1) Lump (local) (1)
Death (1) Hypotension (1) Malaise (3)
Diarrhoea (5) Incontinence (1) Pale mucous membranes (2)
Panting (3)      Tachycardia (1)       Vomiting (66)
Pruritus (1)      Unpleasant taste (1)
Pyrexia (2)       Vocalisation (1)

6.104 FELINE CALICIVIRUS

Feline

<table>
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<th>Year</th>
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<tbody>
<tr>
<td>2015</td>
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<td>5</td>
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</table>

Presenting signs (probable and possible)

| Anaphylaxis (1) | Hypoproteinaemia (1) | Lump (local) (1) |
| Anorexia (5)    | Immune-mediated haemolytic anaemia (1) | Pyrexia (3) |
| Ataxia (1)      | Injection site reaction (1) | |
| Death (1)       | Lame (1) | Swelling (local) (1) |
| Distress (1)    | Lethargy (4) | Tachypnoea (1) |
| Hypersalivation (1) | | |

6.105 FELINE CALICIVIRUS - INACTIVATED

Feline

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Presenting signs (probable and possible)

| Adipsia (1) | Death (3) | Lethargy (13) |
| Alopecia (1) | Diarrhoea (3) | Lump (local) (2) |
| Alopecia (localised) (3) | Distress (1) | Melaena (2) |
| Anaphylaxis (3) | Dyspnoea (2) | Nausea (1) |
| Anorexia (8) | Erythema (3) | Oedema (2) |
| Ataxia (1) | Facial oedema (3) | Pain (5) |
| Cellulitis (1) | Injection site reaction (10) | Pale mucous membranes (1) |
| Collapse (1) | Lame (1) | Pancreatitis (1) |
Paraesthesia (1)  Site reaction (swelling) (1)  Vocalisation (1)
Pruritus (2)  Tachycardia (1)  Vomiting (6)
Pyrexia (10)  Tachypnoea (2)
Site reaction (2)  Unconscious (1)

6.106 FELINE CHLAMYDIA PSITTACI - INACTIVATED

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Presenting signs (probable and possible)
- Adipsia (1)
- Erythema (1)
- Pain (1)
- Anorexia (1)
- Injection site reaction (1)
- Pyrexia (1)
- Ataxia (1)
- Lethargy (1)
- Tachypnoea (1)

6.107 FELINE IMMUNODEFICIENCY VIRUS (PETALUMA STRAIN) - INACTIVE

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Presenting signs (probable and possible)
- Alopecia (1)
- Diarrhoea (1)
- Pyrexia (5)
- Alopecia (localised) (2)
- Erythema (1)
- Site reaction (1)
- Anorexia (4)
- Injection site reaction (5)
- Tachycardia (2)
- Cellulitis (1)
- Lethargy (8)
- Tachypnoea (1)
- Death (1)
- Lump (local) (1)
- Vomiting (3)
- Dehydration (1)
- Oedema (2)
6.108  FELINE IMMUNODEFICIENCY VIRUS (SHIZUOKA STRAIN) - INACTIVE

**Feline**

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**Presenting signs (probable and possible)**

- Alopecia (1)  
- Alopecia (localised) (2)  
- Anorexia (4)  
- Cellulitis (1)  
- Death (1)  
- Dehydration (1)  
- Diarrhoea (1)  
- Erythema (1)  
- Injection site reaction (5)  
- Lethargy (8)  
- Lump (local) (1)  
- Pruritus (1)  
- Pyrexia (5)  
- Site reaction (1)  
- Tachycardia (2)  
- Tachypnoea (1)  
- Vomiting (3)  
- Oedema (2)

6.109  FELINE LEUKAEMIA VIRUS - INACTIVATED

**Feline**

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**Presenting signs (probable and possible)**

- Alopecia (localised) (1)  
- Anorexia (2)  
- Diarrhoea (1)  
- Distress (1)  
- Facial oedema (2)  
- Injection site reaction (2)  
- Lethargy (4)  
- Lump (local) (1)  
- Nausea (1)  
- Pain (1)  
- Pyrexia (3)  
- Pruritus (1)  
- Vomiting (2)
### 6.110 FELINE PANLEUCOPENIA

#### Feline

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<td>5</td>
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**Presenting signs (probable and possible)**

- Anaphylaxis (1)
- Hypoproteinaemia (1)
- Lump (local) (1)
- Anorexia (5)
- Immune-mediated haemolytic anaemia (1)
- Panting (1)
- Ataxia (1)
- Injection site reaction (1)
- Pyrexia (3)
- Death (1)
- Lame (1)
- Swelling (local) (1)
- Distress (1)
- Lethargy (4)
- Tachypnoea (1)
- Hypersalivation (1)
- Vomiting (1)

### 6.111 FELINE PANLEUCOPENIA VIRUS - INACTIVATED

#### Feline

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<td>19</td>
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</table>

**Presenting signs (probable and possible)**

- Adipsia (1)
- Erythema (3)
- Paraesthesia (1)
- Alopecia (1)
- Facial oedema (3)
- Pruritus (2)
- Alopecia (localised) (3)
- Injection site reaction (10)
- Pyrexia (10)
- Anaphylaxis (3)
- Lame (1)
- Site reaction (2)
- Anorexia (8)
- Lethargy (13)
- Site reaction (swelling) (1)
- Ataxia (1)
- Lump (local) (2)
- Tachycardia (1)
- Cellulitis (1)
- Melaena (2)
- Tachypnoea (2)
- Collapse (1)
- Nausea (1)
- Unconscious (1)
- Death (3)
- Oedema (2)
- Vocalisation (1)
- Diarrhoea (3)
- Pain (5)
- Vomiting (6)
- Distress (1)
- Pale mucous membranes (1)
- Dyspnoea (2)
- Pancreatitis (1)
### 6.112 FELINE RHINOTRACHEITIS

**Feline**

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</table>

**Presenting signs (probable and possible)**

- Anaphylaxis (1)
- Death (1)

### 6.113 FELINE RHINOTRACHEITIS VIRUS - INACTIVATED

**Feline**

<table>
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<th>Year</th>
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</table>

**Presenting signs (probable and possible)**

- Adipsia (1)
- Erythema (3)
- Paraesthesia (1)
- Alopecia (1)
- Facial oedema (3)
- Pruritus (2)
- Alopecia (localised) (3)
- Injection site reaction (10)
- Pyrexia (10)
- Anaphylaxis (3)
- Lame (1)
- Site reaction (2)
- Anorexia (8)
- Lethargy (13)
- Site reaction (swelling) (1)
- Ataxia (1)
- Lump (local) (2)
- Tachycardia (1)
- Cellulitis (1)
- Melaena (2)
- Tachypnoea (2)
- Collapse (1)
- Nausea (1)
- Unconscious (1)
- Death (3)
- Oedema (2)
- Vocalisation (1)
- Diarrhoea (3)
- Pain (5)
- Vomiting (6)
- Distress (1)
- Pale mucous membranes (1)
- Dyspnoea (2)
- Pancreatitis (1)
## 6.114 FENBENDAZOLE

### Canine

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<tbody>
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**Presenting signs (probable and possible)**

- Anorexia (3)
- Pale mucous membranes (1)
- Vomiting (6)
- Capillary refill time (slow) (1)
- Pyrexia (1)
- Weight loss (1)
- Collapse (1)
- Tachycardia (1)
- Diarrhoea (4)
- Tachypnoea (1)

### Caprine

<table>
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**Presenting signs (probable and possible)**

- Anorexia (1)
- Drooping (1)
- Diarrhoea (1)
- Weakness (1)

## 6.115 FIPRONIL

### Canine

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**Presenting signs (probable and possible)**

- Alopecia (localised) (1)
- Injection site reaction (2)
- Lump (local) (2)

### Feline

<table>
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**Presenting signs (probable and possible)**

- Alopecia (localised) (1)
6.116 FIROCOXIB

Canine

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Presenting signs (probable and possible)
- Diarrhoea (1)
- Vomiting (2)

6.117 FLUAZURON

Bovine

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Presenting signs (probable and possible)
- Alopecia (1)
- Lesions (1)
- Pruritus (1)

6.118 FLUMETHRIN

Canine

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</table>

Presenting signs (probable and possible)
- Agitation (1)
- Dyspnoea (1)
- Ataxia (1)
- Hypersalivation (1)

6.119 FLUNIXIN MEGLUMINE

Equine

<table>
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<tbody>
<tr>
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</table>

Presenting signs (probable and possible)
- Collapse (2)
FLURALANER

Fluralaner was registered in early 2015. A high number of adverse reports relating to the use of fluralaner were received in the first year. Side effects reported included vomiting, diarrhoea, lethargy, inappetence and itching, and to a much lesser extent, seizures. Media reports and members of the public expressed concern, this in conjunction with limited information available on labels and the reports received caused the APVMA to engage the product registrant to amend their product labels to include additional warnings.

These updated labels are now entering the market and include the following statement:

‘Fluralaner is part of the isoxazoline family of chemicals. Adverse reactions to this family of chemicals are rarely observed but may include vomiting, diarrhoea, lethargy, inappetence, itching and very rarely, seizures. Most adverse reactions are self-limiting and of short duration. If you have any concerns, please speak to your veterinarian.’

### 6.120 FLURALANER

<table>
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<td>2015</td>
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<td>131</td>
<td>124</td>
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</table>

Presenting signs (probable and possible)

- Adipsia (2)
- Agitation (1)
- Alopecia (1)
- Anorexia (16)
- Ataxia (1)
- Behavioural change (1)
- Bloat (1)
- Dehydration (1)
- Diarrhoea (21)
- Disorientation (2)
- Distress (1)
- Elevated ALT (1)
- Erythema (3)
- Flatulence (3)
- Hypersalivation (1)
- Lethargy (23)
- Malaise (4)
- Melaena (2)
- Papules (1)
- Polydipsia (1)
- Pruritus (8)
- Pyrexia (2)
- Retching (1)
- Seizure (1)
- Shaking (1)
- Somnolence (1)
- Vomiting (226)
6.121 FRUSEMIDE

Canine

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<tr>
<th>Year</th>
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<tr>
<td>2015</td>
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Presenting signs (probable and possible)

Vomiting (1)

G GLYCOPROTEIN OF HENDRA VIRUS (SG - PROTEIN)

G Glycoprotein Hendra Virus was first available under permit in 2012. The information received regarding adverse events occurring while the permit was active, were provided to the APVMA under a mandatory reporting regime required as a condition of the permit authorising the supply and use prior to the registration of the product. Please note that a mandatory reporting regime is expected to yield a higher reporting incidence than would be the case under a voluntary reporting arrangement.

In 2015 the product containing this active was registered. At this time the permit condition was lifted and the reporting regime was reverted to voluntary reporting. Thus Veterinarians who used the vaccine where no longer obliged to report adverse effects to the registrant. Reports continue to be made but the frequency of those reports is decreasing.

The most commonly reported presenting signs included lethargy, injection site reaction and anorexia. These symptoms occur occasionally with vaccines of this type. Vaccines act by stimulating an immune response, which protects the animal from serious illnesses. However, this immune response is also responsible for most of the presenting signs observed.

The APVMA notes that vaccines are often used in conjunction with other products (including other vaccines) which could also result in a higher number of reports. In most cases it is not possible to attribute the cause of an adverse reaction to a single active constituent or to any of the products used concurrently. Hence a single report may be classified against multiple active constituents that may have a potential causal relationship with an adverse experience.

For more information about vaccines, go to the APVMA website at www.apvma.gov.au.
### 6.122 G GLYCOPROTEIN OF HENDRA VIRUS (SG - PROTEIN)

#### Equine

<table>
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<tr>
<th>Year</th>
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<td>202</td>
<td>52</td>
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**Presenting signs (probable and possible)**

- Abnormal breathing (2)    
- Abortion (1)              
- Adipsia (2)               
- Aggression (2)            
- Allergy (1)               
- Alopecia (2)              
- Alopecia (localised) (2)  
- Anorexia (54)             
- Anuria (1)                
- Ataxia (10)               
- Behavioural change (3)    
- Coat discoloration (1)    
- Colic (17)                
- Coughing (1)              
- Death (1)                 
- Depression (8)           
- Dermatitis (1)            
- Diarrhoea (1)             
- Epistaxis (1)             
- Facial oedema (1)        
- Fasciculation (1)        
- Hives (3)                
- Injection site reaction (141)  
- Lame (4)                 
- Laminitis (2)            
- Lethargy (84)            
- Listless (5)             
- Lump (local) (18)        
- Malaise (5)              
- Metritis (1)             
- Muscle stiffness (1)     
- Nasal discharge (11)     
- Oedema (24)              
- Pain (68)                
- Polydipsia (2)           
- Pruritus (1)             
- Pyrexia (43)             
- Rash (1)                 
- Recumbency (3)           
- Respiratory problems (2) 
- Shaking (1)              
- Site reaction (swelling) (1)  
- Stiffness (41)           
- Sweating (9)             
- Swelling (local) (78)    
- Tachypnoea (1)           
- Urticaria (11)           
- Walking (difficult) (5)   
- Weakness (2)             
- Weight loss (2)          
- Welts (2)                
- Pain (68)
6.123  GENTAMICIN SULFATE

Canine

<table>
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<tr>
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<td>4</td>
<td>3</td>
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</table>

Presenting signs (probable and possible)
- Anorexia (1)
- Erythema (1)
- Lethargy (1)
- Blisters (1)
- Irritation (ear) (1)
- Malaise (1)
- Deafness (5)
- Irritation (eye) (1)
- Ulceration (1)

6.124  GNRF - PROTEIN CONJUGATE

Porcine

<table>
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<tr>
<th>Year</th>
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<td>1</td>
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Presenting signs (probable and possible)
- Death (1)
- Distress (1)
- Vomiting (1)

6.125  GREEN LIPPED MUSSEL

Canine

<table>
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<tr>
<th>Year</th>
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Presenting signs (probable and possible)
- Anaphylaxis (1)
- Diarrhoea (2)
- Vomiting (1)
- Ataxia (1)
- Melaena (1)
- Death (1)
- QC (1)
6.126 HYDROCORTISONE ACEPONATE

Canine

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Presenting signs (probable and possible)
Deafness (1)

6.127 HYDROCORTISONE ACETATE

Canine

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Presenting signs (probable and possible)
Sneezing (1) Vomiting (2)

6.128 IMEPTOIN

Canine

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<tr>
<th>Year</th>
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<tr>
<td>2015</td>
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</table>

Presenting signs (probable and possible)
Anorexia (1) Collapse (1) Sedation (1)
Ataxia (3) Hyperactivity (2)

IMADACLOPRID

Imidacloprid is a systemic insecticide that acts as an insect neurotoxin and belongs to a class of chemicals called the neonicotinoids which act on the central nervous system of insects. The types of reactions observed and listed here are expected to occur in rare instances.

The most commonly reported presenting signs included site reactions, such as pruritus (itching) and agitation. These are localised reactions related to the application of the product and are generally only observed for a short duration.

Imidacloprid has an extremely high sales volume. The number of reports associated with imidacloprid is low when compared with the number of doses sold in 2015 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.
### 6.129 IMIDACLOPRID

#### Canine

<table>
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<tr>
<td>2015</td>
<td>183</td>
<td>58</td>
<td>125</td>
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#### Presenting signs (probable and possible)

- Abnormal breathing (1)  
- Abscess (2)  
- Adipsia (3)  
- Agitation (35)  
- Allergy (2)  
- Alopecia (6)  
- Alopecia (localised) (8)  
- Anorexia (15)  
- Ataxia (12)  
- Behavioural change (21)  
- Blindness (1)  
- Blister(s) (1)  
- Chemical reaction (unexpected) (1)  
- Coast colour change (2)  
- Collapse (1)  
- Dermatitis (1)  
- Diarrhoea (10)  
- Disorientation (1)  
- Distress (3)  
- Dyspnoea (3)  
- Erythema (26)  
- Excitation (1)  
- Facial oedema (5)  
- Fasciculation (1)  
- Haemorrhage (1)  
- Hives (2)  
- Hyperactivity (4)  
- Hypersalivation (7)  
- Inflammation (3)  
- Insomnia (1)  
- Irritation (eye) (1)  
- Irritation (skin) (4)  
- Lesions (7)  
- Lethargy (56)  
- Lump (local) (1)  
- Malaise (3)  
- Melaena (1)  
- Muscle twitching (6)  
- Odour (1)  
- Pain (2)  
- Panting (8)  
- Paraesthesia (16)  
- Polydipsia (2)  
- Pruritus (62)  
- Pustules (1)  
- Pyoderma (1)  
- Pyrexia (1)  
- Rash (4)  
- Restless (10)  
- Retching (2)  
- Rolling (5)  
- Seizure (1)  
- Self-trauma (28)  
- Shaking (2)  
- Site reaction (71)  
- Site reaction (swelling) (2)  
- Site reaction (swelling) (2)  
- Tachycardia (2)  
- Tachypnoea (3)  
- Tremor (9)  
- Urination (1)  
- Urticaria (2)  
- Vocalisation (6)  
- Vomiting (27)  
- Weight loss (1)  
- Welts (1)
### Feline

<table>
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</table>

**Presenting signs (probable and possible)**

- Adipsia (1)
- Agitation (9)
- Alopecia (8)
- Alopecia (localised) (35)
- Anorexia (13)
- Ataxia (7)
- Behavioural change (9)
- Burn(s) (6)
- Chemical reaction (unexpected) (1)
- Coat colour change (1)
- Comatose (2)
- Defaecation (1)
- Diarrhoea (5)
- Disorientation (1)
- Dyspnoea (1)
- Erythema (13)
- Foaming (1)
- Frothing at the mouth (2)
- Hyperactivity (4)
- Hyperexcitable (1)
- Hypersalivation (18)
- Incontinence (1)
- Irritation (skin) (2)
- Inflammation (1)
- Lesions (7)
- Lethargy (19)
- Lump (local) (1)
- Mydriasis (1)
- Oedema (1)
- Pale mucous membranes (1)
- Paraesthesia (10)
- Polydipsia (1)
- Pruritus (14)
- Pyoderma (1)
- Pyrexia (1)
- Rash (1)
- Seizure (1)
- Self-trauma (2)
- Shaking (1)
- Site reaction (51)
- Tachycardia (2)
- Tremor (1)
- Ulceration (1)
- Vocalisation (3)
- Vomiting (13)

### Ovine

<table>
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<td>2015</td>
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</table>

**Presenting signs (probable and possible)**

- Burn(s) (1)
- Chemical reaction (unexpected) (1)
- Necrosis (1)
- Site reaction (1)
INDOXACARB

Indoxacarb is a widely used systemic parasiticide that disrupts the development cycle of fleas. Indoxacarb is present in a large number of registered veterinary chemical products. It is often present in combination with other active constituents and so has a higher number of reports associated with it.

The most commonly reported presenting signs included site reaction, gastrointestinal signs, vomiting and diarrhoea.

2015 demonstrated an increasing frequency of reactions, particularly in cats. A rising trend for 3 years or repeated frequency over 1 report in 10,000 can initiate regulatory action.

### 6.130 INDOXACARB

**Canine**

<table>
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</table>

**Presenting signs (probable and possible)**

- Alopecia (2)
- Hepatopathy (2)
- Pruritus (28)
- Alopecia (localised) (4)
- Hypersalivation (2)
- Pyoderma (4)
- Anorexia (4)
- Hypotension (2)
- Scabs (2)
- Behavioural change (4)
- Irritation (skin) (4)
- Site reaction (14)
- Coat colour change (2)
- Lesions (8)
- Sneezeing (2)
- Crusting skin (2)
- Lethargy (12)
- Tachycardia (2)
- Dermatitis (4)
- Malaise (2)
- Vocalisation (2)
- Diarrhoea (2)
- Mydriasis (2)
- Vomiting (6)
- Erythema (8)
- Oedema (2)
Feline

<table>
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<td>2015</td>
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<td>46</td>
<td>31</td>
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**Presenting signs (probable and possible)**

- Agitation (8)
- Alopecia (5)
- Alopecia (localised) (18)
- Anorexia (2)
- Ataxia (13)
- Behavioural change (18)
- Blepharitis (1)
- Blindness (2)
- Blurred vision (1)
- Cardiac arrest (1)
- Cardiac arrhythmia (1)
- Circling (1)
- Coat colour change (1)
- Convulsions (1)
- Deafness (1)
- Death (1)
- Diarrhoea (1)
- Disorientation (2)

- Distress (2)
- Dysphagia (1)
- Dyspnoea (1)
- Elevated ALT (1)
- Erythema (2)
- Frothing at the mouth (1)
- Hyperactivity (1)
- Hyperexcitable (1)
- Hypersalivation (12)
- Incontinence (1)
- Incoordination (1)
- Lesions (3)
- Lethargy (7)
- Muscle twitching (2)
- Mydriasis (9)
- Pain (1)
- Panting (1)

- Paraesthesia (3)
- Pruritus (10)
- Restless (1)
- Scabs (1)
- Seizure (5)
- Site reaction (5)
- Skin slough (1)
- Stiffness (1)
- Swelling (local) (1)
- Tachycardia (1)
- Tachypnoea (3)
- Tremor (1)
- Ulceration (1)
- Vocalisation (6)
- Vomiting (9)
- Weakness (1)
6.131 INSULIN

Canine

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Presenting signs (probable and possible)
Injection site reaction (1) Pain (1)

Feline

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Presenting signs (probable and possible)
Blindness (1) Head pressing (1) Hypoglycaemia (1)

6.132 IVERMECTIN

Bovine

<table>
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<tr>
<th>Year</th>
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Presenting signs (probable and possible)
Alopecia (localised) (1) Irritation (skin) (1) Site reaction (1)

Canine

<table>
<thead>
<tr>
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Presenting signs (probable and possible)
Distress (1) Muscle twitching (1) Vomiting (2)
Erythema (1) Pruritus (1)

Equine

<table>
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<th>Year</th>
<th>Total Reports</th>
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<th>Total Possible</th>
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<tbody>
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Presenting signs (probable and possible)
Colic (1)
### 6.133 KETAMINE HYDROCHLORIDE

**Equine**

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<tbody>
<tr>
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**Presenting signs (probable and possible)**

- Low efficacy (2)

### 6.134 LACTIC ACID

**Canine**

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**Presenting signs (probable and possible)**

- Deafness (1)

### 6.135 LASALOCID SODIUM

**Bovine**

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<tr>
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<th>Total Reports</th>
<th>Total Probable</th>
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</table>

**Presenting signs (probable and possible)**

- Paralysis (1)
- Weakness (1)

### 6.136 LEPTOSPIRA ICTEROHAEMORRHAGIAE

**Canine**

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<thead>
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<th>Year</th>
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<th>Total Probable</th>
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<td>2015</td>
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<td>0</td>
<td>2</td>
</tr>
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</table>

**Presenting signs (probable and possible)**

- Agitation (1)
- Lame (1)
- Vomiting (1)
- Haematoma (1)
- Lump (local) (1)
- Injection site reaction (1)
- Shaking (1)
### 6.137 LEPTOSPIRA ICTEROHAEMORRHAGIAE ANTIGEN

**Canine**

<table>
<thead>
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<tbody>
<tr>
<td>2015</td>
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<td>0</td>
<td>6</td>
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</tbody>
</table>

Presenting signs (probable and possible)

- Anaphylaxis (1)
- Injection site reaction (1)
- Rash (1)
- Facial oedema (1)
- Lump (local) (1)
- Swelling (vulva) (1)
- Hives (1)
- Periorbital swelling (1)
- Vomiting (2)

### 6.138 LEVAMISOLE

**Bovine**

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<tr>
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<th>Total Reports</th>
<th>Total Probable</th>
<th>Total Possible</th>
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<tbody>
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<td>2015</td>
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<td>1</td>
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Presenting signs (probable and possible)

- Ataxia (1)
- Collapse (1)

**Canine**

<table>
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<th>Year</th>
<th>Total Reports</th>
<th>Total Probable</th>
<th>Total Possible</th>
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Presenting signs (probable and possible)

- Diarrhoea (2)

**Ovine**

<table>
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<th>Total Probable</th>
<th>Total Possible</th>
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<tbody>
<tr>
<td>2015</td>
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<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

Presenting signs (probable and possible)

- Death (7)
- Malaise (2)
- Spasm (4)
- Lethargy (3)
- Recumbency (1)
- Stiffness (2)
### 6.139 LIGNOCAINE HYDROCHLORIDE

#### Canine

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**Presenting signs (probable and possible)**

- Vomiting (2)

#### Feline

<table>
<thead>
<tr>
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<th>Total Reports</th>
<th>Total Probable</th>
<th>Total Possible</th>
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<tr>
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</tr>
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</table>

**Presenting signs (probable and possible)**

- Ataxia (1)
- Shaking (1)

### 6.140 LIVE FELINE HERPES VIRUS

#### Feline

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Reports</th>
<th>Total Probable</th>
<th>Total Possible</th>
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<tbody>
<tr>
<td>2015</td>
<td>7</td>
<td>2</td>
<td>5</td>
</tr>
</tbody>
</table>

**Presenting signs (probable and possible)**

- Anorexia (5)
- Immune-mediated haemolytic anaemia (1)
- Panting (1)
- Ataxia (1)
- Injection site reaction (1)
- Pyrexia (3)
- Distress (1)
- Lame (1)
- Swelling (local) (1)
- Hypersalivation (1)
- Lethargy (4)
- Tachypnoea (1)
- Hypoproteinaemia (1)
- Lump (local) (1)
- Vomiting (1)
### 6.141 LUfenuron

<table>
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<td>2015</td>
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<td>22</td>
<td>11</td>
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</table>

**Presenting signs (probable and possible)**
- Agitation (1)
- Anorexia (3)
- Behavioural change (1)
- Coughing (2)
- Dermatitis (1)
- Diarrhoea (7)
- Dysphagia (1)
- Erythema (1)
- Hypersalivation (1)
- Lack of effect (2)
- Lethargy (6)
- Panting (1)
- Polydipsia (1)
- Pruritus (4)
- Shaking (1)
- Vomiting (21)

### 6.142 Manganese EDTA

**Bovine**

<table>
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<tr>
<th>Year</th>
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<th>Total Probable</th>
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<td>0</td>
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</tbody>
</table>

**Presenting signs (probable and possible)**
- Injection site reaction (1)
- Site reaction (swelling) (1)

**Ovine**

<table>
<thead>
<tr>
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<th>Total Reports</th>
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</tbody>
</table>

**Presenting signs (probable and possible)**
- Injection site reaction (2)
- Lame (1)
- Lump (local) (2)
### 6.143 MAROPITANT CITRATE

#### Canine

<table>
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</table>

**Presenting signs (probable and possible)**

- Anaemia (2)
- Diarrhoea (6)
- Lethargy (6)
- Tremor (2)
- Vomiting (6)

### 6.144 MELOXICAM

#### Canine

<table>
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<th>Total Probable</th>
<th>Total Possible</th>
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<tbody>
<tr>
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<td>4</td>
</tr>
</tbody>
</table>

**Presenting signs (probable and possible)**

- Anorexia (1)
- Diarrhoea (1)
- Erythema (1)
- Haematemesis (1)
- Anaphylactoid reaction (1)
- Behavioural change (1)
- Ulceration (stomach) (1)
- Depression (1)
- Haematuria (1)
- Azotaemia (1)

#### Feline

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Reports</th>
<th>Total Probable</th>
<th>Total Possible</th>
</tr>
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<td>2015</td>
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<td>4</td>
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</tbody>
</table>

**Presenting signs (probable and possible)**

- Anaphylactoid reaction (1)
- Behavioural change (1)
- Ulceration (stomach) (1)
- Anorexia (3)
- Depression (1)
- Vomiting (2)
- Anuria (1)
- Haematuria (1)
- Azotaemia (1)
- Renal failure (2)
### 6.145 METHADONE HCL

<table>
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</table>

**Presenting signs (probable and possible)**

- Hives (1)  
- Respiratory problems (1)

### 6.146 METHYL LAURATE

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<tbody>
<tr>
<td>2015</td>
<td>9</td>
<td>8</td>
<td>1</td>
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</tbody>
</table>

**Presenting signs (probable and possible)**

- Agitation (1)  
- Facial oedema (1)  
- Rash (1)  
- Alopecia (2)  
- Lesions (3)  
- Site reaction (3)  
- Dermatitis (1)  
- Pruritus (3)  
- Erythema (5)  
- Pyoderma (3)

### 6.147 METHYL LINOLEATE

<table>
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<th>Total Possible</th>
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<tbody>
<tr>
<td>2015</td>
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<td>8</td>
<td>1</td>
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</tbody>
</table>

**Presenting signs (probable and possible)**

- Agitation (1)  
- Facial oedema (1)  
- Rash (1)  
- Alopecia (2)  
- Lesions (3)  
- Site reaction (3)  
- Dermatitis (1)  
- Pruritus (3)  
- Erythema (5)  
- Pyoderma (3)
### 6.148 METHYL MYRISTATE

**Canine**

<table>
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<tbody>
<tr>
<td>2015</td>
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<td>1</td>
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</tbody>
</table>

**Presenting signs (probable and possible)**

- Agitation (1)
- Alopecia (2)
- Dermatitis (1)
- Erythema (5)
- Facial oedema (1)
- Lesions (3)
- Pruritus (3)
- Rash (1)
- Site reaction (3)
- Site reaction (3)
- Pyoderma (3)

### 6.149 METHYL OLEATE

**Canine**

<table>
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<td>2015</td>
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<td>1</td>
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</tbody>
</table>

**Presenting signs (probable and possible)**

- Agitation (1)
- Alopecia (2)
- Dermatitis (1)
- Erythema (5)
- Facial oedema (1)
- Lesions (3)
- Pruritus (3)
- Rash (1)
- Site reaction (3)
- Site reaction (3)
- Pyoderma (3)

### 6.150 METHYL PALMITATE

**Canine**

<table>
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<th>Total Possible</th>
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<tr>
<td>2015</td>
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<td>8</td>
<td>1</td>
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</table>

**Presenting signs (probable and possible)**

- Agitation (1)
- Alopecia (2)
- Dermatitis (1)
- Erythema (5)
- Facial oedema (1)
- Lesions (3)
- Pruritus (3)
- Rash (1)
- Site reaction (3)
- Site reaction (3)
- Pyoderma (3)
### 6.151 METHYL PENTADECANOATE

**Canine**

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<tr>
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<td>2015</td>
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<td>1</td>
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</table>

**Presenting signs (probable and possible)**

- Agitation (1)  
- Alopecia (2)  
- Dermatitis (1)  
- Erythema (5)  
- Facial oedema (1)  
- Lesions (3)  
- Pruritus (3)  
- Rash (1)  
- Site reaction (3)  
- Pyoderma (3)

### 6.152 METHYL STEARATE

**Canine**

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</table>

**Presenting signs (probable and possible)**

- Agitation (1)  
- Alopecia (2)  
- Dermatitis (1)  
- Erythema (5)  
- Facial oedema (1)  
- Lesions (3)  
- Pruritus (3)  
- Rash (1)  
- Site reaction (3)  
- Pyoderma (3)

### 6.153 METHYL PREDNISOLONE ACETATE

**Canine**

<table>
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<tr>
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<td>1</td>
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</table>

**Presenting signs (probable and possible)**

- Anorexia (1)  
- Elevated ALT (1)  
- Lethargy (1)  
- Malaise (1)
6.154 MICONAZOLE NITRATE

Canine

<table>
<thead>
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<th>Year</th>
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<tr>
<td>2015</td>
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</table>

Presenting signs (probable and possible)

- Alopecia (localised) (1)
- Diarrhoea (2)
- Gagging (1)
- Deafness (4)
- Erythema (2)
- Retching (1)

**MILBEMYCIN OXIME**

Milbemycin oxime is a veterinary drug from the group of milbemycins, used as a broad spectrum antiparasitic. It is active against worms (anthelmintic) and mites (miticide). Milbemycin Oxime is present in a number of registered veterinary chemical products in combination with other active constituents and so has a higher number of reports associated with it.

The most commonly reported presenting signs included vomiting and lethargy.

The number of reports associated with milbemycin oxime is low when compared with the number of doses sold in 2015 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

6.155 MILBEMYCIN OXIME

Canine

<table>
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<tr>
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<th>Total Possible</th>
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<td>2015</td>
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<td>105</td>
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</table>

Presenting signs (probable and possible)

- Adipsia (3)
- Dermatitis (3)
- Irritation (skin) (1)
- Agitation (3)
- Diarrhoea (24)
- Lack of effect (5)
- Anorexia (22)
- Distress (2)
- Lethargy (48)
- Ataxia (7)
- Dysphagia (1)
- Lump (local) (2)
- Behavioural change (2)
- Erythema (3)
- Malaise (3)
- Collapse (2)
- Facial oedema (3)
- Melaena (1)
- Convulsions (1)
- Hypersalivation (3)
- Nausea (2)
- Coughing (3)
- Injection site reaction (2)
- Neurological disorder (2)
Pancreatitis (1) Rash (2) Tremor (3)
Panting (1) Retching (4) Unpleasant taste (5)
Periorbital swelling (1) Seizure (3) Vocalisation (1)
Polydipsia (1) Shaking (2) Vomiting (141)
Pruritus (12) Sneezing (1) Weight loss (1)
Pyrexia (3) Tachycardia (1)

**Feline**

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Reports</th>
<th>Total Probable</th>
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<tr>
<td>2015</td>
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<td>17</td>
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</table>

**Presenting signs (probable and possible)**

- Anorexia (5) Lethargy (6) Seizure (1)
- Ataxia (14) Miosis (1) Shaking (2)
- Behavioural change (1) Muscle twitching (3) Somnolence (1)
- Bloat (1) Mydriasis (1) Tachypnoea (1)
- Blurred vision (1) Pain (1) Tremor (4)
- Comatose (2) Panting (1) Unconscious (1)
- Convulsions (1) Paresis (1) Vomiting (2)
- Distress (1) Pyrexia (1) Weakness (1)
- Hypersalivation (2) Recumbency (1)

**6.156 MOMETASONE FUROATE MONOHYDRATE**

**Canine**

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Reports</th>
<th>Total Probable</th>
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<tbody>
<tr>
<td>2015</td>
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<td>0</td>
</tr>
</tbody>
</table>

**Presenting signs (probable and possible)**

- Deafness (1) Irritation (ear) (1)
6.157 MONENSIN SODIUM

Ovine

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Reports</th>
<th>Total Probable</th>
<th>Total Possible</th>
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<tbody>
<tr>
<td>2015</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

Presenting signs (probable and possible)
- Death (3)
- Weakness (3)

MOXIDECTIN

Moxidectin are a broad spectrum parasiticide that disrupts the parasitic nervous system. The types of reactions observed and listed here are expected to occur in rare instances.

The most commonly reported presenting signs included facial oedema, vomiting and lethargy.

The number of reports associated with moxidectin is low when compared with the number of doses sold in 2015 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

6.158 MOXIDECTIN

Bovine

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Reports</th>
<th>Total Probable</th>
<th>Total Possible</th>
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<tbody>
<tr>
<td>2015</td>
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<td>2</td>
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</tr>
</tbody>
</table>

Presenting signs (probable and possible)
- Apnoea (1)
- Hypersalivation (1)
- Ataxia (1)
- Lack of effect (3)

Canine

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Reports</th>
<th>Total Probable</th>
<th>Total Possible</th>
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<tbody>
<tr>
<td>2015</td>
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<td>28</td>
<td>108</td>
</tr>
</tbody>
</table>

Presenting signs (probable and possible)
- Adipsia (2)
- Anaphylactoid reaction (3)
- Behavioural change (6)
- Agitation (11)
- Anaphylaxis (19)
- Blindness (1)
- Allergy (2)
- Anorexia (8)
- Blisters (1)
- Alopecia (2)
- Apnoea (1)
- Bradycardia (5)
- Alopecia (localised) (2)
- Ataxia (8)
- Burn(s) (2)
Capillary refill time (slow) (1)  Hypersalivation (3)  Rash (2)
Chemical reaction (unexpected) (1)  Hypotension (1)  Recumbency (1)
Circulatory collapse (1)  Incontinence (2)  Respiratory problems (1)
Coat colour change (1)  Injection site reaction (16)  Restless (3)
Collapse (9)  Lesions (1)  Seizure (1)
Coughing (2)  Lethargy (36)  Seroma (1)
Defaecation (1)  Lump (local) (9)  Shaking (4)
Diarrhoea (12)  Malaise (7)  Site reaction (10)
Distress (1)  Oedema (2)  Sneezing (2)
Dyspnoea (1)  Pain (8)  Swelling (local) (4)
Erythema (3)  Pale mucous membranes (7)  Tachycardia (1)
Facial oedema (13)  Panting (4)  Tachypnoea (4)
Haematemesis (1)  Paraesthesia (5)  Tremor (3)
Hives (3)  Periorbital swelling (1)  Urticaria (4)
Hyperactivity (4)  Pruritus (10)  Vomiting (62)

Feline

<table>
<thead>
<tr>
<th>Year</th>
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<td>64</td>
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</tbody>
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Presenting signs (probable and possible)

| Adipsia (1) | Burn(s) (5) | Dyspnoea (1) |
| Agitation (8) | Chemical reaction (unexpected) (1) | Erythema (11) |
| Alopecia (7) | Coat colour change (1) | Frothing at the mouth (1) |
| Alopecia (localised) (25) | Comatose (2) | Hyperactivity (3) |
| Anorexia (12) | Defaecation (1) | Hypersalivation (16) |
| Ataxia (7) | Diarrhoea (5) | Incontinence (1) |
| Behavioural change (7) | Disorienation (1) | Irritation (skin) (2) |
Lesions (7)  Polydipsia (1)  Tachycardia (2)
Lethargy (15)  Pruritus (11)  Tremor (1)
Lump (local) (1)  Pyoderma (1)  Ulceration (1)
Mydriasis (1)  Pyrexia (1)  Vocalisation (3)
Oedema (1)  Rash (1)  Vomiting (12)
Pale mucous membranes (1)  Scabs (2)
Paraesthesia (7)  Site reaction (40)

6.159 MOXIDECTIN MICROSPHERES

Canine

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Presenting signs (probable and possible)

Adipsia (1)  Diarrhoea (9)  Paraesthesia (1)
Agitation (5)  Facial oedema (11)  Periorbital swelling (1)
Allergy (1)  Haematemesis (1)  Pruritus (2)
Anaphylactoid reaction (3)  Hives (2)  Pyrexia (8)
Anaphylaxis (19)  Hyperactivity (2)  Rash (2)
Anorexia (3)  Hypersalivation (1)  Recumbency (1)
Apnoea (1)  Hypotension (1)  Respiratory problems (1)
Ataxia (1)  Incontinence (2)  Seroma (1)
Behavioural change (2)  Injection site reaction (16)  Shaking (4)
Blisters (1)  Lethargy (17)  Site reaction (2)
Bradycardia (5)  Lump (local) (9)  Sneezing (2)
Capillary refill time (slow) (1)  Malaise (6)  Swelling (local) (4)
Circulatory collapse (1)  Oedema (2)  Tachycardia (1)
Collapse (8)  Pain (8)  Tachypnoea (4)
Coughing (2)  Pale mucous membranes (7)  Urticaria (3)
Defaecation (1)  Panting (2)  Vomiting (49)
### 6.160 MYCOBACTERIUM PARATUBERCULOSIS

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<tbody>
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**Presenting signs (probable and possible)**
- Anaphylaxis (1)

### Caprine

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<tbody>
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</table>

**Presenting signs (probable and possible)**
- Ataxia (1)
- Death (1)
- Recumbency (1)
- CNS dysfunction (1)
- Nystagmus (1)

### 6.161 MYCOPLASMA HYOPNEUMONIAE - INACTIVATED ANTIGEN

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**Presenting signs (probable and possible)**
- Anaphylaxis (1)
- Death (1)

### 6.162 MYCOPLASMA HYOPNEUMONIAE STRAIN J

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<th>Total Reports</th>
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<td>2015</td>
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**Presenting signs (probable and possible)**
- Collapse (1)
- Lethargy (2)
- Seizure (1)
- Death (2)
- Pyrexia (1)
- Tremor (1)
- Depression (1)
- Recumbency (2)
- Vomiting (1)
### 6.163 Napthalophos

**Ovine**

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Presenting signs (probable and possible)
- Ataxia (1)
- Death (1)
- Weakness (1)

### 6.164 Neomycin

**Feline**

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Presenting signs (probable and possible)
- Anorexia (1)
- Lethargy (1)

### 6.165 Neomycin Sulfate

**Canine**

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Presenting signs (probable and possible)
- Vomiting (3)

### 6.166 Niclosamide

**Canine**

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Presenting signs (probable and possible)
- Diarrhoea (1)
### 6.167 NITENPYRAM

**Canine**

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Presenting signs (probable and possible)
- Agitation (1)
- Lethargy (1)
- Vocalisation (1)
- Convulsions (1)
- Panting (1)
- Lack of effect (1)
- Pruritus (1)

**Feline**

<table>
<thead>
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<th>Year</th>
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Presenting signs (probable and possible)
- Agitation (4)
- Panting (2)
- Seizure (2)
- Anaphylaxis (1)
- Pyrexia (1)
- Tachypnoea (1)
- Diarrhoea (1)
- Respiratory problems (2)
- Vocalisation (2)
- Hyperactivity (1)
- Restless (1)

### 6.168 N-OCTYL BICYCLOHEPTENE DICARBOXIMIDE

**Canine**

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Presenting signs (probable and possible)
- Adipsia (1)
- Ataxia (1)
- Hypersalivation (1)
- Anorexia (1)
- Frothing at the mouth (1)
- Malaise (1)
Feline

<table>
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Presenting signs (probable and possible)
- Ataxia (2) Foaming (3) Pale mucous membranes (1)
- Behavioural change (2) Frothing at the mouth (1) Respiratory problems (1)
- Convulsions (1) Hyperaesthesia (1) Seizure (3)
- Death (1) Hypersalivation (7) Spasm (1)
- Dyspnoea (1) Listless (1) Vomiting (2)

**6.169 OATMEAL EXTRACT**

Canine

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Presenting signs (probable and possible)
- Allergy (1) Pruritus (2)

**6.170 OLEIC ACID**

Feline

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Presenting signs (probable and possible)
- Lethargy (1) Pruritus (1) Sneezing (1)
6.171 OXANTEL EMBONATE

Canine

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Presenting signs (probable and possible)

- Alopecia (1)
- Anorexia (1)
- Diarrhoea (2)
- Erythema (1)
- Lethargy (1)
- Pruritus (1)
- Vomiting (3)

6.172 OXFENDAZOLE

Bovine

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Presenting signs (probable and possible)

- Ataxia (1)
- Collapse (1)

Equine

<table>
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<tr>
<td>2015</td>
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Presenting signs (probable and possible)

- Diarrhoea (1)

Ovine

<table>
<thead>
<tr>
<th>Year</th>
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</table>

Presenting signs (probable and possible)

- Death (2)
- Spasm (2)
### 6.173 OXIBENDAZOLE

**Canine**

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<th>Year</th>
<th>Total Reports</th>
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Presenting signs (probable and possible)
- Diarrhoea (1)

### 6.174 OXYTETRACYCLINE

**Canine**

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<tr>
<th>Year</th>
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<tr>
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</table>

Presenting signs (probable and possible)
- Pyrexia (1)
- Swelling (local) (1)

### 6.175 OXYTETRACYCLINE HYDROCHLORIDE

**Canine**

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<th>Year</th>
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<tbody>
<tr>
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</table>

Presenting signs (probable and possible)
- Pyrexia (1)
- Swelling (local) (1)

### 6.176 PALMITIC ACID

**Feline**

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<th>Year</th>
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Presenting signs (probable and possible)
- Lethargy (1)
- Pruritus (1)
- Sneezing (1)
### 6.177 PARAFFIN

**Porcine**

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</table>

**Presenting signs (probable and possible)**

- Anorexia (1)
- Lethargy (1)
- Seizure (1)
- Death (1)
- Pyrexia (1)
- Site reaction (swelling) (1)
- Injection site reaction (1)
- Recumbency (1)
- Vomiting (1)

### 6.178 PENICILLIN

**Equine**

<table>
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<th>Year</th>
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<td>1</td>
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</table>

**Presenting signs (probable and possible)**

- Convulsions (2)
- Death (2)

### 6.179 PENTOBARBITONE SODIUM

**Canine**

<table>
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<tr>
<th>Year</th>
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<tr>
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</table>

**Presenting signs (probable and possible)**

- Lack of effect (1)

### 6.180 PENTOSAN POLYSULFATE SODIUM

**Canine**

<table>
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<th>Total Reports</th>
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<td>2015</td>
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<td>4</td>
<td>4</td>
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</table>

**Presenting signs (probable and possible)**

- Bradycardia (1)
- Diarrhoea (1)
- Injection site reaction (1)
- Collapse (1)
- Hives (1)
- Lethargy (1)
Lump (local) (1)  Sneezing (1)  Urticaria (1)
Nasal discharge (1)  Swelling (local) (1)  Vomiting (3)
Seroma (1)  Thrombocytopenia (1)  Weakness (1)

Equine

<table>
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<th>Year</th>
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<tr>
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</table>

Presenting signs (probable and possible)
Coat discoloration (1)  Shaking (1)

PERMETHRIN

Permethrin is an insecticide in the pyrethroid family. Pyrethroids are synthetic chemicals that act like natural extracts from the chrysanthemum flower. Permethrin is used in a number of ways to control insects.

Permethrin in high concentrations (such as in topical flea ‘spot-on’ products) is highly toxic to cats. A product-wide label change was implemented in 2011 to address off-label use of dog spot-on products on cats, with the aim of reducing the number of reports relating to exposure of cats to permethrin. Further information on how the APVMA addressed [permethrin toxicity in cats](#) can be found on the APVMA website.

The number of reports associated with permethrin has remained consistently high. It was considered in the majority of cases that the presenting sign accounting for most reports (i.e. skin irritation, pruritus or agitation) involved brief period from which the animal recovered very quickly. In light of this and the fact that the product labels contain warnings regarding expected reactions, no further action was considered necessary other than ongoing monitoring.

### 6.181 PERMETHRIN

Canine

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<tbody>
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<td>42</td>
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Presenting signs (probable and possible)
Abnormal breathing (1)  Alopecia (localised) (7)  Coat colour change (1)
Abscess (1)  Anorexia (18)  Dermatitis (1)
Adipsia (3)  Ataxia (4)  Diarrhoea (10)
Agitation (31)  Behavioural change (17)  Disorientation (1)
Allergy (1)  Blisters (1)  Distress (2)
Alopecia (2)  Burn(s) (4)  Dyspnoea (1)
Erythema (20)  Muscle twitching (6)  Self-trauma (27)
Excitation (1)  Pain (2)  Shaking (2)
Facial oedema (2)  Panting (6)  Site reaction (64)
Fasciculation (2)  Paraesthesia (16)  Site reaction (swelling) (2)
Haemorrhage (1)  Polydipsia (2)  Tachycardia (1)
Hyperactivity (2)  Pruritus (57)  Tachypnoea (1)
Hypersalivation (4)  Pustules (1)  Tremor (7)
Inflammation (4)  Pyoderma (1)  Urination (1)
Insomnia (1)  Pyrexia (1)  Urticaria (1)
Irritation (skin) (5)  Rash (2)  Vocalisation (6)
Lesions (6)  Restless (7)  Vomiting (22)
Lethargy (41)  Retching (2)  Weight loss (2)
Lump (local) (1)  Rolling (5)  Welts (1)
Malaise (3)  Scabs (2)

6.182  PERNA CANALICULUS

Canine

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Presenting signs (probable and possible)
Diarhoea (2)  Melaena (1)

6.183  PHENOBARBITONE

Canine

<table>
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Presenting signs (probable and possible)
Seizure (1)  Tremor (1)
### 6.184 PIMELIC ACID

**Feline**

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Presenting signs (probable and possible)
- Lethargy (1)
- Pruritus (1)
- Sneezing (1)

### 6.185 PIMOBENDAN

**Canine**

<table>
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</table>

Presenting signs (probable and possible)
- Diarrhoea (1)
- Haemorrhage (1)
- Melaena (2)

### 6.186 PIPERONYL BUTOXIDE

**Canine**

<table>
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</table>

Presenting signs (probable and possible)
- Adipsia (1)
- Ataxia (1)
- Hypersalivation (1)
- Anorexia (1)
- Frothing at the mouth (1)
- Malaise (1)
### Feline

<table>
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#### Presenting signs (probable and possible)

- Alopecia (1)
- Ataxia (3)
- Behavioural change (2)
- Convulsions (1)
- Death (1)
- Diarrhoea (1)
- Dyspnoea (1)
- Foaming (3)
- Frothing at the mouth (1)
- Hyperaesthesia (1)
- Hypersalivation (7)
- Listless (1)
- Pruritus (1)
- Respiratory problems (1)
- Seizure (3)
- Shaking (1)
- Spasm (1)
- Vomiting (3)

### 6.187 PIROCTONE OLAMINE

#### Canine

<table>
<thead>
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<th>Total Possible</th>
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<tbody>
<tr>
<td>2015</td>
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#### Presenting signs (probable and possible)

- Allergy (1)
- Erythema (1)
- Pruritus (1)

### 6.188 POLYMIXIN B

#### Feline

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#### Presenting signs (probable and possible)

- Anorexia (1)
- Lethargy (1)
### 6.189 POLYMYXIN B SULFATE

**Canine**

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**Presenting signs (probable and possible)**
- Alopecia (localised) (1)
- Diarrhoea (2)
- Vomiting (1)
- Deafness (2)
- Erythema (2)

### 6.190 PORCINE CIRCOVIRUS TYPE 2 ORF2 PROTEIN

**Porcine**

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**Presenting signs (probable and possible)**
- Anaphylaxis (1)
- Lethargy (1)
- Seizure (1)
- Death (2)
- Recumbency (1)
- Vomiting (1)

### 6.191 PORCINE CIRCOVIRUS TYPE 2 ORF2 SUBUNIT ANTIGEN

**Porcine**

<table>
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**Presenting signs (probable and possible)**
- Anorexia (1)
- Lethargy (1)
- Seizure (1)
- Death (1)
- Pyrexia (1)
- Site reaction (swelling) (1)
- Injection site reaction (1)
- Recumbency (1)
- Vomiting (1)
PRAZIQUANTEL

Praziquantel is a systemic anthelmintic chemical primarily used to treat worm infections in domestic animals. The most commonly reported presenting signs included vomiting, lethargy and diarrhoea. It is used in many products and has a very high sales volume.

The number of reports associated with praziquantel is low when compared with the number of doses sold in 2015 (less than 1 in 10,000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

6.192 PRAZIQUANTEL

Canine

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<th>Year</th>
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<td>66</td>
<td>115</td>
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Presenting signs (probable and possible)

- Adipsia (1)
- Erythema (5)
- Polydipsia (1)
- Agitation (3)
- Facial oedema (1)
- Pruritus (14)
- Alopecia (1)
- Hyperactivity (4)
- Pyrexia (3)
- Anaphylaxis (1)
- Hypersalivation (2)
- Rash (1)
- Anorexia (15)
- Hypotension (1)
- Respiratory problems (1)
- Ataxia (2)
- Incontinence (1)
- Retching (2)
- Behavioural change (2)
- Injection site reaction (3)
- Seizure (2)
- Capillary refill time (slow) (1)
- Irritation (skin) (1)
- Shaking (1)
- Collapse (4)
- Lack of effect (5)
- Sneezing (1)
- Convulsions (1)
- Lethargy (29)
- Tachycardia (2)
- Coughing (3)
- Lump (local) (3)
- Tachypnoea (1)
- Dermatitis (1)
- Malaise (5)
- Unpleasant taste (1)
- Diarrhoea (23)
- Melaena (1)
- Vocalisation (1)
- Distress (1)
- Pale mucous membranes (2)
- Vomiting (135)
- Dysphagia (1)
- Panting (4)
- Weight loss (1)
Equine

<table>
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<th>Total Possible</th>
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Presenting signs (probable and possible)

Colic (1)

Feline

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Presenting signs (probable and possible)

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<th>Recumbency (1)</th>
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<tr>
<td>Alopecia (localised) (1)</td>
<td>Lethargy (13)</td>
<td>Seizure (1)</td>
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<tr>
<td>Anorexia (8)</td>
<td>Listless (1)</td>
<td>Shaking (2)</td>
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<tr>
<td>Ataxia (20)</td>
<td>Miosis (1)</td>
<td>Site reaction (6)</td>
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<tr>
<td>Behavioural change (1)</td>
<td>Muscle twitching (3)</td>
<td>Somnolence (1)</td>
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<tr>
<td>Bloat (1)</td>
<td>Mydriasis (1)</td>
<td>Tachypnoea (2)</td>
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<tr>
<td>Blurred vision (1)</td>
<td>Pain (2)</td>
<td>Tremor (5)</td>
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<tr>
<td>Comatose (2)</td>
<td>Panting (1)</td>
<td>Unconscious (1)</td>
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<tr>
<td>Convulsions (1)</td>
<td>Paresis (1)</td>
<td>Vomiting (5)</td>
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<td>Diarrhoea (2)</td>
<td>Pruritus (1)</td>
<td>Weakness (1)</td>
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<td>Distress (1)</td>
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6.193 PRENISOLONE

Canine

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Presenting signs (probable and possible)

<table>
<thead>
<tr>
<th>Alopecia (localised) (1)</th>
<th>Diarrhoea (2)</th>
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<tr>
<td>Deafness (2)</td>
<td>Erythema (2)</td>
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6.194 PROCAINE HYDROCHLORIDE

Equine

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Presenting signs (probable and possible)
Convulsions (1)  Death (1)

6.195 PROPENTOFYLLINE

Canine

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</table>

Presenting signs (probable and possible)
Anuria (1)  Incontinence (1)  Polydipsia (1)

6.196 PROPOFOL

Canine

<table>
<thead>
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<tr>
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</table>

Presenting signs (probable and possible)
Apnoea (1)  Erythema (1)  Urticaria (2)
Bradycardia (1)  Hives (1)  Wheals (1)
6.197 PROPOXUR

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Reports</th>
<th>Total Probable</th>
<th>Total Possible</th>
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<tr>
<td>2015</td>
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<td>2</td>
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</tbody>
</table>

Presenting signs (probable and possible)
- Agitation (1)
- Dyspnoea (1)
- Ataxia (1)
- Hypersalivation (1)

PYRANTEL EMBONATE

Pyrantel embonate is a systemic anthelmintic chemical primarily used to treat worm infections in domestic animals. It is a very commonly used active and is present in many different dog and cat worming products. The most commonly reported presenting signs included vomiting, lethargy and diarrhoea. It works by making the worms unable to move (paralyzed) so that the body can remove them naturally in the stool.

The number of reports associated with Pyrantel embonate is low when compared with the number of doses sold in 2015 (less than 1 in 10,000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

6.198 PYRANTEL EMBONATE

<table>
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<tr>
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<td>65</td>
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</table>

Presenting signs (probable and possible)
- Agitation (2)
- Hyperactivity (8)
- Panting (6)
- Alopecia (1)
- Hypersalivation (2)
- Pruritus (3)
- Anaphylaxis (2)
- Hypotension (2)
- Pyrexia (5)
- Anorexia (6)
- Incontinence (2)
- Tachycardia (3)
- Capillary refill time (slow) (1)
- Injection site reaction (2)
- Tachypnoea (1)
- Collapse (7)
- Lethargy (14)
- Unpleasant taste (2)
- Death (1)
- Low efficacy (2)
- Vocalisation (2)
- Diarrhoea (16)
- Lump (local) (2)
- Vomiting (141)
- Erythema (3)
- Malaise (6)
- Weight loss (1)
- Facial oedema (2)
- Pale mucous membranes (4)
### Equine

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Reports</th>
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<th>Total Possible</th>
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</table>

Presenting signs (probable and possible)

- Colic (2)
- Diarrhoea (2)

### Feline

<table>
<thead>
<tr>
<th>Year</th>
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<td>2015</td>
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Presenting signs (probable and possible)

- Anorexia (2)
- Lethargy (7)
- Tachypnoea (2)
- Ataxia (10)
- Pain (2)
- Tremor (1)
- Diarrhoea (1)
- Pyrexia (4)
- Vomiting (2)
- Hypersalivation (3)
- Site reaction (2)

### 6.199 PYRETHRIN

### Canine

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<th>Total Possible</th>
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<tbody>
<tr>
<td>2015</td>
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<td>1</td>
<td>1</td>
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</table>

Presenting signs (probable and possible)

- Adipsia (3)
- Ataxia (3)
- Hypersalivation (3)
- Anorexia (3)
- Frothing at the mouth (1)
- Malaise (3)
## Feline

<table>
<thead>
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<tr>
<td>2015</td>
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<td>8</td>
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</table>

### Presenting signs (probable and possible)

- Alopecia (1)
- Foaming (3)
- Pruritus (1)
- Ataxia (5)
- Frothing at the mouth (3)
- Respiratory problems (2)
- Behavioural change (2)
- Hyperaesthesia (3)
- Seizure (5)
- Convulsions (1)
- Hypersalivation (13)
- Shaking (1)
- Death (1)
- Listless (1)
- Spasm (3)
- Diarrhoea (1)
- Pale mucous membranes (1)
- Vomiting (3)
- Dyspnoea (1)
- Paraesthesia (1)

### 6.200 PYRETHRUM EXTRACT

#### Feline

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<td>2</td>
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### Presenting signs (probable and possible)

- Ataxia (1)
- Dyspnoea (1)
- Vomiting (1)
- Behavioural change (1)
- Pale mucous membranes (1)
- Diarrhoea (1)
- Shaking (1)

### 6.201 PYRIPROXYFEN

#### Canine

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### Presenting signs (probable and possible)

- Agitation (1)
- Paraesthesia (1)
### Feline

<table>
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**Presenting signs (probable and possible)**

- Hypersalivation (2)
- Pruritus (2)
- Incontinence (2)
- Tremor (2)

**6.202 QUIL**

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<td>1</td>
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</table>

**Presenting signs (probable and possible)**

- Anorexia (1)
- Lethargy (1)
- Pyrexia (1)

**6.203 RABBIT CALICIVIRUS DISEASE VIRUS -INACTIVATED**

<table>
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**Presenting signs (probable and possible)**

- Anaphylaxis (1)
- Death (2)
- Dyspnoea (1)
- Anorexia (1)
- Diarrhoea (1)
- Lethargy (1)

**6.204 RECOMBINANT GP70 SUB-TYPE A**

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**Presenting signs (probable and possible)**

- Anorexia (1)
- Lethargy (1)
- Pyrexia (1)
6.205 ROBENACOXIB

Canine

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Presenting signs (probable and possible)
- Behavioural change (1)
- Lethargy (1)
- Coughing (1)
- Vomiting (2)

Feline

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<th>Total Possible</th>
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Presenting signs (probable and possible)
- Behavioural change (1)

6.206 SALICYLIC ACID

Canine

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Presenting signs (probable and possible)
- Deafness (1)
6.207 SELAMECTIN

Feline

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Presenting signs (probable and possible)
- Agitation (4)
- Alopecia (1)
- Alopecia (localised) (25)
- Anisocoria (1)
- Ataxia (1)
- Dermatitis (1)
- Erythema (8)
- Frothing at the mouth (1)
- Hives (1)
- Hypersalivation (1)
- Lack of effect (1)
- Lethargy (1)
- Malaise (1)
- Pain (2)
- Pruritus (6)
- Scabs (2)
- Site reaction (27)
- Vomiting (4)
- Welts (1)

6.208 SELENIUM

Bovine

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Presenting signs (probable and possible)
- Anorexia (1)
- Hypersalivation (1)
- Lethargy (1)
6.209 SELENIUM AS SODIUM SELENATE

Bovine

<table>
<thead>
<tr>
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<tbody>
<tr>
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Presenting signs (probable and possible)
- Ataxia (1)
- Collapse (1)

Ovine

<table>
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<tr>
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Presenting signs (probable and possible)
- Death (4)
- Malaise (1)
- Spasm (2)
- Lethargy (2)
- Recumbency (1)
- Stiffness (1)

6.210 SELENIUM AS SODIUM SELENITE

Bovine

<table>
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Presenting signs (probable and possible)
- Injection site reaction (1)
- Site reaction (swelling) (1)

Ovine

<table>
<thead>
<tr>
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<th>Total Probable</th>
<th>Total Possible</th>
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<tbody>
<tr>
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<td>1</td>
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</table>

Presenting signs (probable and possible)
- Injection site reaction (2)
- Lame (1)
- Lump (local) (2)
### 6.211 SHARK CARTILAGE

**Canine**

<table>
<thead>
<tr>
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<tr>
<td>2015</td>
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</table>

Presenting signs (probable and possible)

- Diarrhoea (2)
- Melaena (1)
- Pruritus (2)

### 6.212 SODIUM FLUOROCETATE

**Canine**

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>2015</td>
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<td>2</td>
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Presenting signs (probable and possible)

- Death (4)
- Poisoning (1)
- Vocalisation (2)
- Frothing at the mouth (2)
- Seizure (2)

### 6.213 SODIUM SELENATE

**Bovine**

<table>
<thead>
<tr>
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<th>Total Reports</th>
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Presenting signs (probable and possible)

- Ataxia (1)
- Collapse (1)

**Ovine**

<table>
<thead>
<tr>
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<th>Total Reports</th>
<th>Total Probable</th>
<th>Total Possible</th>
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</table>

Presenting signs (probable and possible)

- Death (2)
- Malaise (1)
- Stiffness (1)
- Lethargy (2)
- Recumbency (1)
6.214 SODIUM SELENITE

Ovine

<table>
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<tbody>
<tr>
<td>2015</td>
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</table>

Presenting signs (probable and possible)
- Injection site reaction (2)
- Lame (1)
- Lump (local) (2)

SPINOSAD

Spinosad is an insecticidal chemical that disrupts the insect nervous system. The most commonly reported presenting signs included vomiting, lethargy, anorexia and diarrhoea.

Vomiting is a known side effect and is recorded on the label. Vomiting is of short duration only involving a single instance from which the animal recovers quickly. In light of this and the fact that the product labels contain warnings regarding expected reactions, no further action was considered necessary other than ongoing monitoring.

6.215 SPINOSAD

Canine

<table>
<thead>
<tr>
<th>Year</th>
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</table>

Presenting signs (probable and possible)
- Adipsia (3)
- Dysphagia (1)
- Malaise (5)
- Agitation (3)
- Erythema (1)
- Mydriasis (1)
- Anaphylactoid reaction (1)
- Facial oedema (4)
- Nausea (4)
- Anorexia (24)
- Flatulence (3)
- Neurological disorder (2)
- Ataxia (14)
- Gagging (1)
- Pancreatitis (1)
- Behavioural change (1)
- Hyperaesthesia (2)
- Periorbital swelling (1)
- Collapse (2)
- Hypersalivation (9)
- Pruritus (5)
- Constipation (1)
- Hypersensitive to stimuli (1)
- Pyrexia (4)
- Dermatitis (3)
- Irritation (skin) (1)
- QC (1)
- Diarrhoea (30)
- Lack of effect (2)
- Rash (1)
- Distress (2)
- Lethargy (57)
- Regurgitation (1)
Restless (2)  Tachycardia (1)  Vomiting (220)
Retching (2)  Tremor (9)  Weight loss (2)
Seizure (3)  Unpleasant taste (8)  Welts (1)
Shaking (3)  Vocalisation (3)

Feline

<table>
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<tr>
<th>Year</th>
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<th>Total Probable</th>
<th>Total Possible</th>
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<td>58</td>
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Presenting signs (probable and possible)

- Abnormal breathing (1)  Hyperactivity (1)  Pruritus (3)
- Agitation (3)  Hypersalivation (7)  Pyrexia (3)
- Anorexia (6)  Lame (1)  Recumbency (1)
- Ataxia (19)  Lethargy (21)  Restless (3)
- Behavioural change (2)  Malaise (2)  Shaking (2)
- Bloat (1)  Miosis (1)  Somnolence (2)
- CNS dysfunction (1)  Muscle twitching (4)  Tachypnoea (1)
- Collapse (1)  Mydriasis (1)  Tremor (6)
- Comatose (2)  Nystagmus (1)  Vocalisation (1)
- Diarrhoea (4)  Panting (1)  Vomiting (87)
- Disorientation (1)  Paresis (1)  Weakness (1)
- Distress (1)  Polydipsia (1)
- Erythema (2)  Proprioception deficit (1)
6.216  STREPTOCOCCUS EQUI AS CELL FREE EXTRACT

Equine

<table>
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Presenting signs (probable and possible)

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<td>Ataxia (1)</td>
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<td>Coat colour change (1)</td>
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<tr>
<td>Colic (1)</td>
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<td>Death (1)</td>
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<tr>
<td>Diarrhoea (1)</td>
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<tr>
<td>Inflammation (1)</td>
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<tr>
<td>Injection site reaction (16)</td>
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<td>Lethargy (8)</td>
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<td>Oedema (11)</td>
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<td>Pain (4)</td>
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<td>Pyrexia (2)</td>
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<td>Stiffness (5)</td>
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<td>Sweating (1)</td>
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<td>Swelling (local) (4)</td>
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<td>Urticaria (1)</td>
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6.217  SYNTHETIC ANALOGUE OF F3 FRACTION FELINE FACIAL PHEROMONE

Feline

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Presenting signs (probable and possible)

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<td>Pruritus (1)</td>
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<tr>
<td>Sneezing (1)</td>
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6.218  SYNTHETIC ANALOGUE OF THE CANINE APPEASING PHEROMONE

Canine

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Presenting signs (probable and possible)

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<td>Facial oedema (1)</td>
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<td>Alopecia (2)</td>
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<td>Dermatitis (1)</td>
<td>Pruritus (3)</td>
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<td>Erythema (5)</td>
<td>Pyoderma (3)</td>
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### 6.219 TELMISARTAN

**Feline**

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Presenting signs (probable and possible)

- Diarrhoea (1)

### 6.220 TEMEPHOS

**Ovine**

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Presenting signs (probable and possible)

- Lame (1)

### 6.221 THIAMAZOLE

**Feline**

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Presenting signs (probable and possible)

- Abnormal Biochemistry (1)
- Hepatopathy (1)
- Malaise (2)
- Anorexia (3)
- Jaundice (1)
- Restless (1)
- Elevated ALP (1)
- Lethargy (2)
- Vomiting (3)
- Elevated ALT (1)
- Leukopenia (1)
- Weight loss (1)

### 6.222 TILETAMINE AS THE HYDROCHLORIDE

**Canine**

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Presenting signs (probable and possible)

- Recovery (prolonged) (1)
6.223 TILUDRONIC ACID AS DISODIUM TILUDRONATE

Equine

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Presenting signs (probable and possible)
- Anorexia (1)
- Polydipsia (1)

6.224 TITANIUM DIOXIDE

Canine

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Presenting signs (probable and possible)
- Erythema (1)
- Site reaction (1)
- Ulceration (1)

6.225 TRICLABENDAZOLE

Bovine

<table>
<thead>
<tr>
<th>Year</th>
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<tbody>
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Presenting signs (probable and possible)
- Lack of effect (1)

6.226 XYLAZINE HYDROCHLORIDE

Equine

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<th>Year</th>
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Presenting signs (probable and possible)
- Injection site reaction (1)
- Swelling (local) (1)
- Urticaria (1)
6.227 ZETA-CYPERMETHRIN

Bovine

<table>
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Presenting signs (probable and possible)
- Agitation (1)

6.228 ZINC AS ZINC DISODIUM EDTA

Bovine

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Presenting signs (probable and possible)
- Injection site reaction (1)
- Site reaction (swelling) (1)

Ovine

<table>
<thead>
<tr>
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Presenting signs (probable and possible)
- Injection site reaction (2)
- Lame (1)
- Lump (local) (2)

6.229 ZINC OXIDE

Canine

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</table>

Presenting signs (probable and possible)
- Erythema (1)
- Site reaction (1)
- Ulceration (1)

6.230 ZOLAZEPAM AS THE HYDROCHLORIDE

Canine

<table>
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Presenting signs (probable and possible)
- Recovery (prolonged) (1)
<table>
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<td>ACEPROMAZINE MALEATE</td>
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<td>BENZALKONIUM CHLORIDE</td>
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<td>BORDETELLA</td>
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