Australian Government
Australian Pesticides and
Veterinary Medicines Authority

# REPORT OF ADVERSE EXPERIENCES

# FOR VETERINARY MEDICINES AND AGRICULTURAL CHEMICALS

# 2013

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# EXECUTIVE SUMMARY

## Adverse Experience Reporting Program (AERP)

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

The AERP assesses and classifies reports of adverse experiences from exposure to, the 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 AERP, including farmers, pet owners, gardeners, veterinarians or the general public.

The AERP assesses each report of an adverse experience. It then classifies the relationship between the veterinary medicine or agricultural chemical product and the adverse experience. This may see the APVMA confirm the registration of a product as safe and effective, or it may 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, the APVMA may cancel registration of a product and remove it from the market.

## Assessments and classification in 2013

This report summarises the findings of AERP assessments of adverse experiences reports in 2013.

The APVMA assessed and classified 3733 adverse experience reports involving registered veterinary medicines. Of these adverse experience reports, 80 per cent involved animal safety, 17 per cent involved lack of efficacy and 3 per cent involved human health issues.

The APVMA assessed and classified 50 adverse experiences involving agricultural chemical products. Of these, 54 per cent involved effects on crops or animals, 36 per cent involved human health issues, and 10 per cent involved effects on the environment.

The APVMA assessed 135 reports relating to adverse experiences from registered veterinary medicines and agricultural chemicals involving effects on human health. Of these, 21 were classified as *probable or possible*, 99 as *off-label* (used contrary to label instructions) and 15 as *unlikely or unknown*.

No adverse experience assessed and classified by the APVMA in 2013 required a major regulatory action against any registered product.

## More information

For more information about the AERP, contact the APVMA:

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# 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 any 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 2013 involving registered veterinary medicines and adverse experiences relating to animals.

**Chapter 4** sets out the results of AERP assessments involving registered veterinary medicines and effects relating to humans.

**Chapter 5** sets out the results of AERP assessments involving registered agricultural chemical products and adverse experiences not involving humans. This includes crop damage, domestic animal harm, environmental damage or lack of efficacy.

**Chapter 6** sets out the results of APVMA assessments involving registered agricultural chemicals and effects relating to humans.

**A Glossary** of terms and **Index** of active constituents are provided at the end of this report.

# 1 INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian government statutory authority that manages the National Registration Scheme for veterinary medicines and agricultural chemical products.

It ensures these products are suitable for use in Australian conditions and feature appropriate label instructions and warnings for their effective use without harming people, crops, animals or the environment.

The definitions of veterinary medicines and agricultural chemical products, as defined by the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code) are:

- **Veterinary medicines** – all veterinary chemical products such as vaccines, antibiotics, parasiticides (for worms, lice, fleas and ticks), anti-inflammatory and anti-arthritic agents, nutritional supplements, therapeutic pet foods and diets for companion (pet) and production (agricultural) animals.
- **Pesticides and agricultural chemicals** – agricultural and household chemicals (such as insecticides, herbicides and fungicides) water treatment products (including swimming pool products), products for treating algae and mould, and products for preventing rot and infestation in marine structures.

The APVMA registers veterinary medicines and agricultural chemical products prior to sale, and regulates these products up to and including the point of sale.

The APVMA also operates post-registration programs to monitor the safety and performance of these products in Australia throughout their lifecycle.

## 1.1 Adverse Experience Reporting Program (AERP)

The APVMA Adverse Experience Reporting Program (AERP) is a post-registration program that assesses reports of adverse experiences associated with the use of a registered veterinary medicine or agricultural chemical product when the product is used according to label instructions.

Recording, assessing and classifying adverse experiences is vital for detecting uncommon events not evident during the initial registration process of a product. The program provides a means of facilitating regulatory action that may be necessary to assure the continued safety, quality and effectiveness of registered products.

There are two components to the AERP: the ***AERP Vet*** for registered veterinary medicines, and the ***AERP Ag*** for registered agricultural chemicals.

### Definitions of an adverse experience

#### *AERP Vet adverse experience*

An unintended or unexpected effect on animals, human beings or the environment, or lack of efficacy associated with the use of a registered veterinary chemical product when used according to label instructions.

#### *AERP Ag adverse experience*

An unintended or unexpected effect on plants, plant products, animals, human beings or the environment or lack of efficacy associated with the use of an agricultural chemical product when used according to label instructions.

## 1.2 Reporting an adverse experience

Anyone can report an adverse experience to the AERP. This includes veterinarians, animal owners, farmers, gardeners, agronomists, health workers, state and territory authorities or members of the public.

Registrants of veterinary medicines and agricultural chemicals have a legal obligation to report any adverse events to the APVMA from the use of their registered product. Under Section 161 of the *Agvet Code,* registrants must provide the APVMA with any new information that comes to their attention. This new information may include information on adverse human health effects, harm to animals, damage to plants, property or the environment, or lack of efficacy when the products are used according to label instructions. The registrant reporting component of AERP *Vet* and AERP *Ag* is one method by which registrants can meet certain legislative obligations of Section 161 of the *Agvet Code.*

The APVMA encourages the reporting of all adverse experiences with a veterinary medicine or agricultural chemical product. This includes 'off-label' incidents (where instructions for use or warnings were not correctly followed or heeded). More information about reporting off-label adverse experiences is provided below.

Even adverse experiences that are listed on a product label as a possible side effect should be reported, as this allows the APVMA to maintain records of these incidents and better understand their true incidence.

### Reporting off-label adverse experiences

The scope of the AERP does not cover reports involving the off-label use of registered products and therefore these adverse experiences are not included in this report. However, the APVMA encourages the reporting of off-label adverse experiences as these have occasionally highlighted potentially significant issues with registered products, including:

- Treatment protocols involving the administration of production animal products to companion animals, inconsistent with label instructions, have resulted in illness or death of the treated animal.
- The use of dog products on cats can cause serious adverse effects. This action is clearly off-label and the public should be aware that certain constituents (such as high concentration permethrin) are toxic to cats.

- Spray drift can result in environmental damage or human exposure from chemical application contrary to label instructions.
- Accidental human exposure to veterinary medicines, particularly injectable products (such as vaccines) can cause unpleasant and potentially harmful adverse experiences.

## 1.3 Assessing an adverse experience

The APVMA assesses every adverse experience reported.

- Reports made directly to the APVMA by non-registrants (voluntary reports) are copied to the product registrant, who is then required to evaluate each report. The registrant may contact the reporting person or the attending veterinarian to help determine if any follow-up work is required.
- The product registrant must subsequently report its findings to the APVMA, which then assesses it to determine if further information is required. In some cases, additional expert opinion is sought from other government agencies such as the Office of Chemical Safety (OCS) and the Department of the Environment, universities, the Australian Veterinary Association, or other appropriate authorities.
- The APVMA also considers any scientific information or information about a registered product that is published or provided by an equivalent agency in another country.
- It considers if the product was used according to label instructions or if the use was off-label.
- The APVMA applies a standard methodology to classify the relationship between a reported adverse experience and exposure to or use of a product. More information on how the APVMA classifies the relationship is provided below.
- Trend analyses may be performed periodically or if a cluster of reports is submitted involving a particular product. This may see the APVMA confirm the registration of a product, or allow it to continue with changes to how the product can be used (and therefore require a change to label instructions and warnings). The APVMA may also cancel the registration of a chemical and remove a product from the market. More information on possible actions the APVMA may take is provided below.
- The APVMA advises everyone who reports an adverse experience of the outcome of its assessment and classification, including any regulatory action or ongoing monitoring activities.
- If an adverse experience is reported directly to a product registrant, the registrant must provide a report to the APVMA (registrant report). The APVMA assesses this report to determine if any further laboratory, pathology or veterinary work is required before it classifies an adverse experience.

## 1.4 Classifying an adverse experience

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

## 1.5 Responding to classifications

The APVMA may take various actions in response to its assessment and classification of an adverse experience report. These actions include but are not limited to:

- Amending the conditions of a product registration, such as requiring changes to label instructions or warnings.
- Suspending and/or cancelling the registration of a product.
- Reviewing the active constituent of a product under the APVMA's Chemical Review Program.
- Referring for action, such as compliance action or referral to state authorities for action.
- Educational and promotional activities, such as providing scientific papers or articles on issues identified with a particular product to relevant journals, magazines or newspapers. When required, education is also provided to the veterinary profession, farming community or the general public about safe and effective use of a product.

### Regulatory action

The APVMA considers a broad range of issues and options when deciding what, if any, regulatory action is required to ensure registered veterinary medicines and agricultural chemical products sold in Australia are safe and effective.

- For each registered veterinary medicine, the APVMA conducts an analysis of all adverse experience reports received. All reports classified as *probable* or *possible* are compared with the total number of doses sold within the relevant financial year and a 'reporting incidence' is calculated (i.e. the number of adverse experience reports per number of doses sold). A control limit or 'warning line' for reporting incidence figures which indicate that further action may be required is one or more per 10 000 doses sold[1].
- The APVMA may take regulatory action if, for a particular product:
  - the reporting incidence is greater than one per 10 000 in two out of three consecutive years
  - an exceptional incidence of three or more per 10 000 occurs on any one occasion, or
  - a consistent rising trend is seen over 5 years (irrespective of the reporting incidence).
- The APVMA also considers available scientific literature and information relating to trend analysis and risk assessment when determining if regulatory action is required.

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[1] *Final Report to the Veterinary Products Committee*. Department for Environment, Food & Rural Affairs, United Kingdom, 2002.

- In addition, the APVMA considers if the noted presenting signs (adverse experiences) are listed in warning statements on the product label, in which case a higher reporting incidence may be acceptable. It also considers the severity of presenting signs (more severe signs may trigger regulatory action at a lower reporting incidence).

## 1.6 Assessments and classifications in 2013

In 2013, a total of 3733 adverse experience reports involving registered veterinary products were assessed and classified.

- Of these adverse experience reports, 80 per cent involved animal safety, 17 per cent involved lack of efficacy and 3 per cent involved human health issues (Figure 1).
- Of the 3733 adverse experiences reports assessed under the AERP *Vet*, 2338 were classified as either *probable* or *possible*.

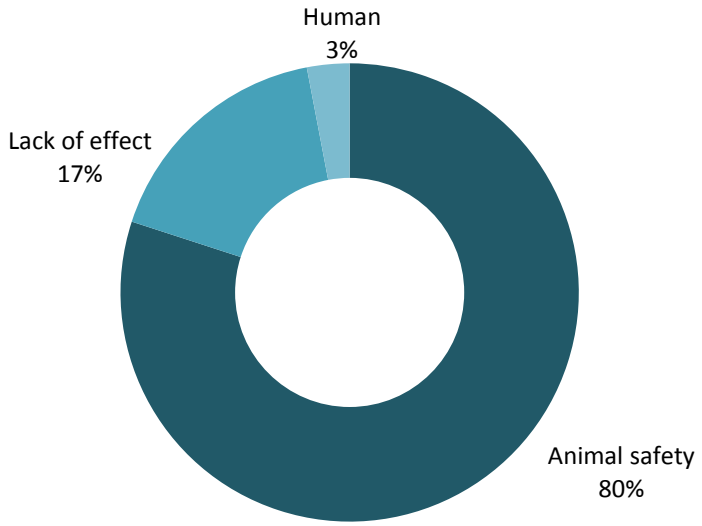


**Figure 1. Adverse experience reports involving registered veterinary medicines processed and finalised in 2013.**

In 2013, a total of 50 adverse experience reports involving agricultural products were assessed and classified.

- Of these adverse experience reports processed and classified, 54 per cent involved effects on crops or animals, 36 per cent involved human health issues, and 10 per cent involved effects on the environment (Figure 2).
- Of the 50 reports assessed under the AERP *Ag*, 19 were classified as *probable* or *possible.*

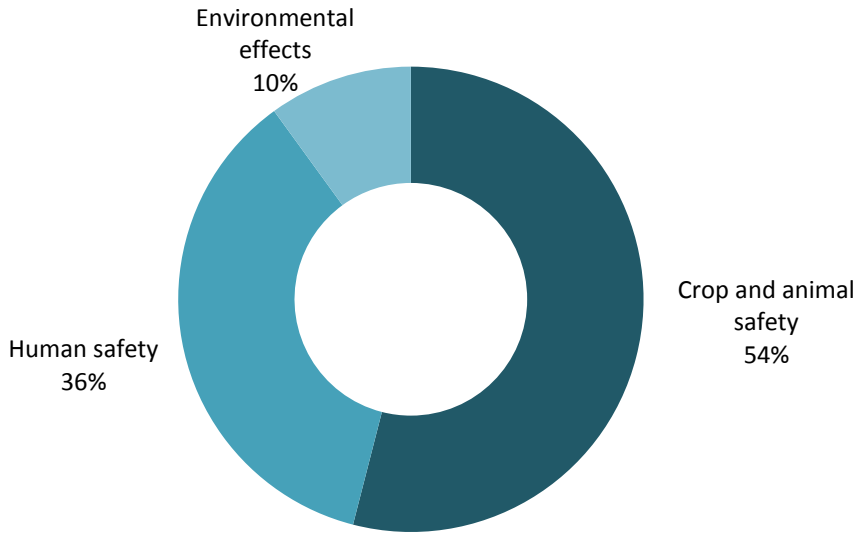


**Figure 2. Adverse experience reports involving registered agriculture chemicals processed and finalised in 2013.**

A total of 135 adverse experiences involving effects on humans from registered veterinary medicines and agricultural chemical products were reported in 2013. Of these, 21 were classified as *probable* or *possible*, 99 were classified as *off-label* and 15 were classified as *unlikely* or *unknown*.

No adverse experience assessed and classified by the APVMA in 2013 required a 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.

# 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 order of frequency.

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.

Data in this report *should not* be used to:

- associate adverse effects with a particular registered veterinary medicine or agricultural chemical product
- assess the safety and efficacy of a product or an active constituent that it contains
- establish an acceptable frequency of occurrence of an adverse experience, or
- compare one product or active constituent with another product or active constituent.

## 2.1 Interpreting the data correctly

There is a range of considerations that must be taken into account when interpreting data in this report.

- **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.

- **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.

- **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 lethargy
- one report also listed a death.

- **The number of reports listed under an active constituent gives no indication as to the 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.

## 2.2 Example

### Active constituent A

#### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 2 | 1 |

**Presenting signs (probable and possible)**

Injection site reaction (3)

Anorexia (3)

Lethargy (2)

Death (1)

### Active constituent B

#### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 1 | 1 |

**Presenting signs (probable and possible)**

Death (1)

Injection site reaction (1)

## Active constituent C

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 1 | 2 |

**Presenting signs (probable and possible)**

Anorexia (3)
Death (1)

# 3 VETERINARY MEDICINES—ANIMALS

This chapter summarises classifications of APVMA assessments of adverse experience reports involving registered veterinary medicines in 2013.

The APVMA assessed and classified 3733 adverse experience involving registered veterinary medicines in 2013. The largest proportion of reports involved animal safety (80%) followed by lack of efficacy (17%).

No regulatory action was required for active constituents involving veterinary medicines and animals in 2013, as the frequency of adverse experience reports received was relatively low compared with the total number of doses sold. The number of doses sold is used to estimate the size of the treated populations.

See Chapter 2: How to read this report for more information on how to interpret data in this chapter correctly, and what the data should not be used for.

## Abamectin

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 1 | 1 |

**Presenting signs (probable and possible)**

Crusting skin (1)
Lesions (1)
Site reaction (1)
Wheals (1)

### *Equine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 1 | 1 |

**Presenting signs (probable and possible)**

Anorexia(1)
Gingival soreness (1)
Lethargy (1)
Pawing at ground (1)
Shaking (1)

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 37 | 26 | 11 |

**Presenting signs (probable and possible)**

Wool damage (21)
Death (13)
Lack of effect (2)
Convulsions (1)
Disorientation (1)
Erythema (1)
Frothing at the mouth (1)
Lesions (1)
Muscle stiffness (1)
Scabs (1)
Weakness (1)

## Acetyl glucosamine

### *Equine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Equine Pyrexia (1)
Swelling (local) (1)

## Agelpristone

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 5 | 5 | 0 |

**Presenting signs (probable and possible)**

Lack of effect (5)

## Albendazole

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 15 | 4 | 11 |

**Presenting signs (probable and possible)**

Death (15)
Lethargy (2)
Anorexia (1)
Convulsions (1)
Disorientation (1)
Frothing at the mouth (1)
Frothing at the nose (1)
Hypersalivation (1)
Muscle stiffness (1)
Recumbency (1)
Weakness (1)

## Alpha-cypermethrin

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Lack of effect (1)

## Alphaxalone

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 13 | 0 | 13 |

**Presenting signs (probable and possible)**

Bradycardia (3)
Recovery (poor) (3)
Apnoea (2)
Death (2)
Swelling (local) (2)
Cardiac arrest (1)
Cyanosis (1)
Dyspnoea (1)
Erythema (1)
Injected mucous membranes (1)
Low efficacy (1)
Oedema (1)
Periorbital swelling (1)
Recovery (prolonged) (1)
Seizure (1)
Vomiting (1)

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 10 | 1 | 9 |

**Presenting signs (probable and possible)**

Respiratory problems (3)
Anisocoria (2)
Cardiac arrest (2)
Death (2)
Pulmonary oedema (2)
Tremor (2)
Apnoea (1)
Diarrhoea (1)
Hypersalivation (1)
Oedema (1)
Swelling (local) (1)
Vomiting (1)

## Aluminium hydroxide

Aluminium hydroxide is a compound commonly used as an adjuvant in vaccines. It stabilises vaccine proteins, preventing the vaccine from adhering to the glass container. It is also thought to enhance the immune response to vaccination. Because this active constituent is present in a number of vaccine products, it is reasonable to expect a larger number of reports to be associated with its use. The most commonly reported presenting sign was the occurrence of an injection site reaction.

For more information about vaccines, go to the APVMA website at www.apvma.gov.au.

## Aluminium hydroxide

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 28 | 2 | 26 |

**Presenting signs (probable and possible)**

Injection site reaction (20)
Malaise (4)
Lethargy (3)
Anorexia (2)
Collapse (2)
Cyanosis (2)
Hypotension (2)
Immune-mediated haemolytic anaemia (2)
Pruritis (2)
Anaphylaxis (1)
Facial oedema (1)
Lump (local) (1)
Oedema (1)
Pyrexia (1)
Respiratory problems (1)
Urticaria (1)
Vomiting (1)

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Anaphylactoid reaction (1)

Death (1)

## Amitraz

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 4 | 1 | 3 |

**Presenting signs (probable and possible)**

Lack of effect (3)

Ataxia (1)

Disorientation (1)

Tremor (1)

## Amoxycillin as Amoxycillin trihydrate

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 5 | 2 | 3 |

**Presenting signs (probable and possible)**

Oedema (3)

Injection site reaction (2)

Anaphylaxis (1)

Hypotension (1)

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Allergy (1)

Oedema (1)

## Amphotericin B

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Anorexia (1) Injection site reaction (1) Lethargy (1)

### *Anaplasma centrale*

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Lack of effect (18) Vaccination reaction (2)

## Atipamezole hydrochloride

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 3 | 0 |

**Presenting signs (probable and possible)**

Hypersalivation (3) Panting (1)

### *Babesia bigemina*

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 20 | 2 | 18 |

**Presenting signs (probable and possible)**

Lack of effect (18) Vaccination reaction (2)

## *Babesia bovis*

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 20 | 2 | 18 |

**Presenting signs (probable and possible)**

Lack of effect (18)
Vaccination reaction (2)

## Benazepril hydrochloride

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 2 | 1 |

**Presenting signs (probable and possible)**

Anorexia (2)
Vomiting (2)
Nystagmus (1)
Recumbency (2)
Head tilt (1)
Pruritis (1)

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 1 | 1 |

**Presenting signs (probable and possible)**

Anorexia (2)

## Betamethasone valerate

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Irritation (skin) (1)

## *Bordetella 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 include coughing, lethargy and injection-site reaction (inactivated, cell-free vaccine) and facial oedema and vomiting (killed vaccine). 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 *Bordetella bronchiseptica* vaccine strains is low when compared with the number of doses sold in 2013 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

For more information about canine vaccines, go to the APVMA website at www.apvma.gov.au.

## *Bordetella bronchiseptica*

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 149 | 45 | 104 |

**Presenting signs (probable and possible)**

Injection site reaction (45)
Coughing (30)
Sneezing (21)
Lethargy (18)
Facial oedema (15)
Anorexia (11)
Nasal discharge (11)
Vomiting (11)
Pain (5)
Respiratory problems (5)
Swelling (local) (5)
Anaphylactoid reaction (4)
Diarrhoea (4)
Pneumonia (3)
Anaphylaxis (2)
Conjunctivitis (2)
Ocular discharge (2)
Pharyngitis (2)
Pruritis (2)
Arthropathy (1)
Bronchitis (1)
Defaecation (1)
Epiphora (1)
Hepatopathy (1)
Inflammation (1)
Listless (1)
Lump (local) (1)
Lymphadenopathy (1)
Megaoesophagus (1)
Oedema (1)
Polyarthritis (1)
Pyrexia (1)
Shaking (1)
Sweating (1)
Swollen ears and face (1)
Swollen lips and face (1)
Tonsillitis (1)
Urticaria (1)
Weakness (1)
Wheals (1)

## *Bordetella bronchiseptica* (inactivated cell free extract)

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 46 | 5 | 41 |

**Presenting signs (probable and possible)**

Injection site reaction (21)
Lethargy (14)
Pain (9)
Vomiting (7)
Pyrexia (6)
Anorexia (4)
Malaise (4)
Oedema (3)
Pruritis (3)
Allergy (2)
Anaphylaxis (2)
Ataxia (2)
Collapse (2)
Cyanosis (2)
Facial oedema (2)
Hypotension (2)
Immune-mediated haemolytic anaemia (2)
Respiratory problems (2)
Urticaria (2)
Behavioural change (1)
Coughing (1)
Inflammation (1)
Lump (local) (1)
Site reaction (swelling) (1)
Unconscious (1)
Vocalisation (1)

## *Bordetella bronchiseptica* killed vaccine

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 59 | 0 | 59 |

**Presenting signs (probable and possible)**

Anaphylactoid reaction (17)
Facial oedema (17)
Anaphylaxis (7)
Vomiting (7)
Collapse (6)
Pruritis (6)
Urticaria (6)
Injection site reaction (4)
Pale mucous membranes (3)
Pyrexia (3)
Agitation (2)
Bradycardia (2)
Erythema (2)
Red eyes (2)
Swollen lips and face (2)
Tachycardia (2)
Tachypnoea (2)
Ataxia (1)
Cyanosis (1)
Immune-mediated haemolytic anaemia (1)
Lethargy (1)
Pyoderma (1)
Rash (1)
Thrombocytopenia (1)
Vocalisation (1)

## Bovine coronavirus (inactivated)

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 2 | 0 |

**Presenting signs (probable and possible)**

Malaise (2)
Milk production decrease (2)
Injection site reaction (1)
Pyrexia (1)

## Bovine ephemeral fever virus (BEFV)

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 0 | 2 |

**Presenting signs (probable and possible)**

Lack of effect (2)
Ataxia (1)

## Bovine rotavirus (NCDV)

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 2 | 0 |

**Presenting signs (probable and possible)**

Malaise (2)
Milk production decrease (2)
Injection site reaction (1)
Pyrexia (1)

## Butorphanol base as Butorphanol tartrate

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Injection site reaction (1)

## *Campylobacter fetus* (*Vibrio fetus*)

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Anorexia (1) Lethargy (1)

## *Campylobacter fetus venerealis* biotype intermedius subt1

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Anorexia (1) Lethargy (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 include facial oedema, vomiting, lethargy, injection site reaction, anaphylactoid 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 adenovirus vaccine strains vaccine strains is low when compared with the number of doses sold in 2013 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

For more information about canine vaccines, go to the APVMA website at www.apvma.gov.au.

## Canine adenovirus type 2

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 186 | 13 | 173 |

**Presenting signs (probable and possible)**

Facial oedema (34)
Vomiting (20)
Lethargy (18)
Anaphylactoid reaction (17)
Coughing (15)
Injection site reaction (10)
Nasal discharge (10)
Sneezing (10)
Anaphylaxis (9)
Pain (8)
Pyrexia (8)
Urticaria (7)
Pruritis (6)
Anorexia (5)
Collapse (5)
Ataxia (4)
Diarrhoea (3)
Respiratory problems (3)
Swollen ears and face (3)
Agitation (2)
Epiphora (2)
Erythema (2)
Pale mucous membranes (2)
Pharyngitis (2)
Polyarthritis (2)
Red eyes (2)
Swollen lips and face (2)
Tachycardia (2)
Tachypnoea (2)
Allergy (1)
Behavioural change (1)
Bradycardia (1)
Bronchitis (1)
Cyanosis (1)
Death (1)
Dyspnoea (1)
Haemorrhagic gastroenteritis (1)
Hepatopathy (1)
Immune-mediated haemolytic anaemia (1)
Inflammation (1)
Lump (local) (1)
Lymphadenopathy (1)
Megaoesophagus (1)
Oedema (1)
Pneumonia (1)
Pyoderma (1)
Rash (1)
Shaking (1)
Site reaction (swelling) (1)
Thrombocytopenia (1)
Tonsillitis (1)
Unconscious (1)

## Canine adenovirus type 2 - live (infectious hepatitis)

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 33 | 1 | 32 |

**Presenting signs (probable and possible)**

Injection site reaction (20)
Lack of effect (4)
Malaise (4)
Collapse (3)
Lethargy (3)
Anorexia (2)
Cyanosis (2)
Hypotension (2)
Immune-mediated haemolytic anaemia (2)
Anaphylaxis (1)
Facial oedema (1)
Hypothermia (1)
Pale mucous membranes (1)
Pruritis (1)
Pyrexia (1)
Respiratory problems (1)
Urticaria (1)
Vasculitis (1)
Vomiting (1)

## Canine adenovirus type 2 live (CAV II)

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | | 1 |

**Presenting signs (probable and possible)**

Anorexia (1)
Lethargy (1)
Vomiting (1)

## Canine adenovirus type 2 strain Manhattan - live

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 55 | 0 | 55 |

**Presenting signs (probable and possible)**

Lack of effect (24)
Injection site reaction (18)
Lethargy (8)
Anorexia (6)
Pain (4)
Swelling (local) (4)
Vomiting (4)
Diarrhoea (2)
Anaphylactoid reaction (1)
Arthropathy (1)
Facial oedema (1)
Listless (1)
Oedema (1)
Pruritis (1)
Sweating (1)
Swollen lips and face (1)
Weakness (1)
Wheals (1)

### Canine coronavirus vaccine - antigen

#### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 5 | 1 | 4 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Vomiting (4) | Facial oedema (1) | Swelling (local) (1) |
| Lethargy (3) | Injection site reaction (1) | |

## Canine distemper virus vaccines

Canine distemper virus (in various strains) is a constituent of 'core' canine vaccine products that target common canine systemic illness. Core vaccines protect animals from severe, life-threatening diseases with which have worldwide distribution.

The most commonly reported presenting signs include lack of effect, lethargy, injection site reaction, facial oedema and vomiting. 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 distemper virus vaccine strains is low when compared with the number of doses sold in 2013 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

For more information about canine vaccines, go to the APVMA website at www.apvma.gov.au.

## Canine distemper virus

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 130 | 5 | 125 |

**Presenting signs (probable and possible)**

Lack of effect (47)
Facial oedema (28)
Anaphylactoid reaction (17)
Vomiting (12)
Anaphylaxis (8)
Injection site reaction (8)
Lethargy (6)
Urticaria (6)
Collapse (5)
Pruritis (5)
Pyrexia (3)
Agitation (2)
Ataxia (2)
Erythema (2)
Pale mucous membranes (2)
Red eyes (2)
Swollen ears and face (2) Swollen lips and face (2)
Tachycardia (2)
Tachypnoea (2)
Anorexia (1)
Bradycardia (1)
Cyanosis (1)
Death (1)
Diarrhoea (1)
Dyspnoea (1)
Epiphora (1)
Immune-mediated haemolytic anaemia (1)
Lump (local) (1)
Megaoesophagus (1)
Nasal discharge (1)
Polyarthritis (1)
Pyoderma (1)
Rash (1)
Shaking (1)
Sneezing (1)
Thrombocytopenia (1)

## Canine distemper virus - living

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 57 | 4 | 53 |

**Presenting signs (probable and possible)**

Injection site reaction (22)
Lethargy (13)
Lack of effect (11)
Vomiting (9)
Pain (8)
Anorexia (5)
Pyrexia (5)
Malaise (4)
Collapse (3)
Anaphylaxis (2)
Ataxia (2)
Cyanosis (2)
Facial oedema (2)
Hypotension (2)
Immune-mediated haemolytic anaemia (2)
Pruritis (2)
Allergy (1)
Behavioural change (1)
Diarrhoea (1)
Haemorrhagic gastroenteritis (1)
Hepatopathy (1)
Hypothermia (1)
Inflammation (1)
Oedema (1)
Pale mucous membranes (1)
Respiratory problems (1)
Site reaction (swelling) (1)
Unconscious (1)
Urticaria (1)
Vasculitis (1)

### Canine distemper virus strain Onderstepoort

#### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 55 | 0 | 55 |

**Presenting signs (probable and possible)Lethargy (9)**

| | | |
|---|---|---|
| Lack of effect (24) | Vomiting (4) | Oedema (1) |
| Injection site reaction (18) | Diarrhoea (2) | Pruritis (1) |
| Lethargy (8) | Anaphylactoid reaction (1) | Sweating (1) |
| Anorexia (6) | Arthropathy (1) | Swollen lips and face (1) |
| Pain (4) | Facial oedema (1) | Weakness (1) |
| Swelling (local) (4) | Listless (1) | Wheals (1) |

## 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 include 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 low when compared with the number of doses sold in 2013 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions. For more information about canine vaccines, go to the APVMA website at www.apvma.gov.au.

## Canine parainfluenza

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 33 | 5 | 28 |

**Presenting signs (probable and possible)**

Coughing (15)
Nasal discharge (9)
Sneezing (9)
Facial oedema (5)
Lethargy (3)
Respiratory problems (3)
Anorexia (2)
Pharyngitis (2)
Bronchitis (1)
Diarrhoea (1)
Epiphora (1)
Lymphadenopathy (1)
Pneumonia (1)
Polyarthritis (1)
Pyrexia (1)
Swollen ears and face (1)
Tonsillitis (1)
Urticaria (1)
Vomiting (1)

## Canine parainfluenza virus type 2

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 90 | 4 | 86 |

**Presenting signs (probable and possible)**

Lack of effect (24)
Facial oedema (22)
Anaphylactoid reaction (18)
Pruritis (8)
Anaphylaxis (7)
Vomiting (7)
Collapse (6)
Injection site reaction (6)
Urticaria (5)
Pale mucous membranes (3)
Pyrexia (3)
Agitation (2)
Bradycardia (2)
Erythema (2)
Red eyes (2)
Swollen lips and face (2)
Tachycardia (2)
Tachypnoea (2)
Ataxia (1)
Cyanosis (1)
Immune-mediated haemolytic anaemia (1)
Lethargy (1)
Pyoderma (1)
Rash (1)
Thrombocytopenia (1)
Vocalisation (1)

## Canine parainfluenza virus

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 126 | 41 | 85 |

**Presenting signs (probable and possible)**

Injection site reaction (45)
Lethargy (25)
Vomiting (16)
Coughing (14)
Pain (13)
Sneezing (12)
Anorexia (11)
Facial oedema (7)
Swelling (local) (5)
Anaphylactoid reaction (4)
Pyrexia (4)
Anaphylaxis (3)
Diarrhoea (3)
Ataxia (2)
Conjunctivitis (2)
Nasal discharge (2)
Ocular discharge (2)
Oedema (2)
Pneumonia (2)
Pruritis (2)
Respiratory problems (2)
Allergy (1)
Arthropathy (1)
Behavioural change (1)
Defaecation (1)
Hepatopathy (1)
Inflammation (1)
Listless (1)
Lump (local) (1)
Megaoesophagus (1)
Shaking (1)
Site reaction (swelling) (1)
Sweating (1)
Swollen lips and face (1)
Unconscious (1)
Weakness (1)
Wheals (1)

## Canine parainfluenza virus - inactivated

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 28 | 2 | 26 |

**Presenting signs (probable and possible)**

Injection site reaction (20)
Malaise (4)
Lethargy (3)
Anorexia (2)
Collapse (2)
Cyanosis (2)
Hypotension (2)
Immune-mediated haemolytic anaemia (2)
Pruritis (2)
Anaphylaxis (1)
Facial oedema (1)
Lump (local) (1)
Oedema (1)
Pyrexia (1)
Respiratory problems (1)
Urticaria (1)
Vomiting (1)

## Canine parvovirus vaccines

Canine parvovirus strains are 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 include 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 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 low when compared with the number of doses sold in 2013 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

For more information about canine vaccines, go to the APVMA website at www.apvma.gov.au.

## Canine parvovirus

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 130 | 5 | 125 |

**Presenting signs (probable and possible)**

Lack of effect (47)
Facial oedema (28)
Anaphylactoid reaction (17)
Vomiting (12)
Anaphylaxis (8)
Injection site reaction (8)
Lethargy (6)
Urticaria (6)
Collapse (5)
Pruritis (5)
Pyrexia (3)
Agitation (2)
Ataxia (2)
Erythema (2)
Pale mucous membranes (2)
Red eyes (2)
Swollen ears and face (2)
Swollen lips and face (2)
Tachycardia (2)
Tachypnoea (2)
Anorexia (1)
Bradycardia (1)
Cyanosis (1)
Death (1)
Diarrhoea (1)
Dyspnoea (1)
Epiphora (1)
Immune-mediated haemolytic anaemia (1)
Lump (local) (1)
Megaoesophagus (1)
Nasal discharge (1)
Polyarthritis (1)
Pyoderma (1)
Rash (1)
Shaking (1)
Sneezing (1)
Thrombocytopenia (1)

## Canine parvovirus type 2

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 24 | 3 | 21 |

**Presenting signs (probable and possible)**

Lethargy (10)
Pain (8)
Vomiting (8)
Lack of effect (7)
Pyrexia (4)
Anorexia (3)
Ataxia (2)
Injection site reaction (2)
Allergy (1)
Anaphylaxis (1)
Behavioural change (1)
Diarrhoea (1)
Facial oedema (1)
Haemorrhagic gastroenteritis (1)
Hepatopathy (1)
Inflammation (1)
Oedema (1)
Pruritis (1)
Site reaction (swelling) (1)
Unconscious (1)

## Canine parvovirus - live

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 33 | 1 | 32 |

**Presenting signs (probable and possible)**

Injection site reaction (20)
Lack of effect (4)
Malaise (4)
Collapse (3)
Lethargy (3)
Anorexia (2)
Cyanosis (2)
Hypotension (2)
Immune-mediated haemolytic anaemia (2)
Anaphylaxis (1)
Facial oedema (1)
Hypothermia (1)
Pale mucous membranes (1)
Pruritis (1)
Pyrexia (1)
Respiratory problems (1)
Urticaria (1)
Vasculitis (1)
Vomiting (1)

## Canine parvovirus (inactivated)

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Anorexia (1)
Lack of effect (1)
Vomiting (1)

## Canine parvovirus strain 154 - live

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 55 | 0 | 55 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Lack of effect (24) | Vomiting (4) | Oedema (1) |
| Injection site reaction (18) | Diarrhoea (2) | Pruritis (1) |
| Lethargy (8) | Anaphylactoid reaction (1) | Sweating (1) |
| Anorexia (6) | Arthropathy (1) | Swollen lips and face (1) |
| Pain (4) | Facial oedema (1) | Weakness (1) |
| Swelling (local) (4) | Listless (1) | Wheals (1) |

## Carnitine - L

### *Equine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 2 | 0 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Anorexia (1) | Pyrexia (1) | Tachycardia (1) |
| Lethargy (1) | Shaking (1) | |

## Carprofen

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 7 | 0 | 7 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Lethargy (3) | Anorexia (1) | Hyperactivity (1) |
| Ataxia (2) | Deafness (1) | Injection site reaction (1) |
| Aggression (1) | Haemorrhagic gastroenteritis (1) | Pruritis (1) |
| Anaphylaxis (1) | Hives (1) | Vomiting (1) |

## Cefovecin as sodium salt

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 2 | 0 |

**Presenting signs (probable and possible)**

Anaphylactoid reaction (1)
Injection site reaction (1)

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 13 | 2 | 11 |

**Presenting signs (probable and possible)**

Lack of effect (4)
Anaphylactoid reaction (2)
Vomiting (2)
Allergy (1)
Anaphylaxis (1)
Anisocoria (1)
Blood in faeces (1)
Bradycardia (1)
Collapse (1)
Death (1)
Diarrhoea (1)
Haemorrhagic gastroenteritis (1)
Hypothermia (1)
Injection site reaction (1)
Lethargy (1)
Oedema (1)
Pain (1)
Shock (1)
Tachypnoea (1)

### *Guinea Pig*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Anorexia (1)
Diarrhoea (1)
Lethargy (1)

## Cephalexin as Cephalexin monohydrate

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Erythema multiforme (1)
Vomiting (1)

## *Chlamydophilia felis* inactivated

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 6 | 2 | 4 |

**Presenting signs (probable and possible)**

Pyrexia (5)
Anorexia (3)
Lethargy (3)
Injection site reaction (2)
Alopecia (localised) (1)
Dehydration (1)
Dermatitis (1)
Pain (1)
Pruritis (1)
Shaking (1)
Swelling (local) (1)

## Chlorfenvinphos

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 0 | 3 |

**Presenting signs (probable and possible)**

Lack of effect (3)

## Chondroitin sulfate

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 5 | 1 | 4 |

**Presenting signs (probable and possible)**

Vomiting (3)
Diarrhoea (2)
Lethargy (2)
Behavioural change (1)

## Clavulanic acid as Potassium clavulanate

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 5 | 2 | 3 |

**Presenting signs (probable and possible)**

Oedema (3)
Injection site reaction (2)
Anaphylaxis (1)
Hypotension (1)

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Allergy (1)
Oedema (1)

## Clomipramine hydrochloride

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 4 | 0 | 4 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Hyperactivity (3) | Behavioural change (2) | Distress (2) |

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 18 | 11 | 7 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Lethargy (12) | Adipsia (2) | Constipation (1) |
| Urinary retention (11) | Vocalisation (2) | Dysphonia (1) |
| Stranguria (9) | Vomiting (2) | Incontinence (1) |
| Anorexia (4) | Behavioural change (1) | |

## *Clostridium chauvoei*—Formol culture

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 4 | 2 | 2 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Allergy (1) | Lump (local) (1) | Vaginitis (1) |
| Anaphylaxis (1) | Milk production decrease (1) | |
| Death (1) | Oedema (1) | |

### *Caprine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Injection site reaction (1) Oedema (1) Pain (1)

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 3 | 0 |

**Presenting signs (probable and possible)**

Injection site reaction (2) Ataxia (1) Shaking (1)

Abscess (1) Death (1)

## *Clostridium chauvoei*—killed

### *Caprine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Death (1) Diarrhoea (1) Lethargy (1)

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Injection site reaction (1) Lame (1)

## *Clostridium chauvoei*—toxoid

### *Caprine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Death (1) Diarrhoea (1) Lethargy (1)

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Injection site reaction (1) Lame (1)

## *Clostridium chauvoei* whole cell culture

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Injection site reaction (1)

## *Clostridium haemolyticum*

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Injection site reaction (1)

## *Clostridium novyi* type B toxoid and inactivated cells

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Injection site reaction (1)

## *Clostridium novyi* type B - killed

### *Caprine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Death (1)
Diarrhoea (1)
Lethargy (1)

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Injection site reaction (1)
Lame (1)

## *Clostridium novyi* type B - toxoid

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 4 | 2 | 2 |

**Presenting signs (probable and possible)**

Allergy (1)
Anaphylaxis (1)
Death (1)
Lump (local) (1)
Milk production decrease (1)
Oedema (1)
Vaginitis (1)

### *Caprine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 0 | 2 |

**Presenting signs (probable and possible)**

Death (1)
Diarrhoea (1)
Injection site reaction (1)
Lethargy (1)
Oedema (1)
Pain (1)

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 4 | 4 | 0 |

**Presenting signs (probable and possible)**

Injection site reaction (3)
Abscess (1)
Ataxia (1)
Death (1)
Lame (1)
Shaking (1)

## *Clostridium perfringens* type B toxoid

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Injection site reaction (1)

## *Clostridium perfringens* type C toxoid

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 3 | 0 |

**Presenting signs (probable and possible)**

Injection site reaction (2)
Malaise (2)
Milk production decrease (2)
Pyrexia (1)

## *Clostridium perfringens* type D toxoid

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 7 | 5 | 2 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Milk production decrease (3) | Anaphylaxis (1) | Pyrexia (1) |
| Injection site reaction (2) | Death (1) | Vaginitis (1) |
| Malaise (2) | Lump (local) (1) | |
| Allergy (1) | Oedema (1) | |

### *Caprine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 1 | 2 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Death (1) | Lack of effect (1) | Pain (1) |
| Diarrhoea (1) | Lethargy (1) | |
| Injection site reaction (1) | Oedema (1) | |

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 4 | 4 | 0 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Injection site reaction (3) | Ataxia (1) | Lame (1) |
| Abscess (1) | Death (1) | Shaking (1) |

## *Clostridium septicum* - toxoid

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 5 | 3 | 2 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Allergy (1) | Injection site reaction (1) | Oedema (1) |
| Anaphylaxis (1) | Lump (local) (1) | Vaginitis (1) |
| Death (1) | Milk production decrease (1) | |

### *Caprine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 0 | 2 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Death (1) | Injection site reaction (1) | Oedema (1) |
| Diarrhoea (1) | Lethargy (1) | Pain (1) |

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 4 | 4 | 0 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Injection site reaction (3) | Ataxia (1) | Lame (1) |
| Abscess (1) | Death (1) | Shaking (1) |

## *Clostridium tetani* - toxoid

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 5 | 3 | 2 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Allergy (1) | Injection site reaction (1) | Oedema (1) |
| Anaphylaxis (1) | Lump (local) (1) | Vaginitis (1) |
| Death (1) | Milk production decrease (1) | |

### *Caprine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 1 | 2 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Death (1) | Lack of effect (1) | Pain (1) |
| Diarrhoea (1) | Lethargy (1) | |
| Injection site reaction (1) | Oedema (1) | |

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 4 | 4 | 0 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Injection site reaction (3) | Ataxia (1) | Lame (1) |
| Abscess (1) | Death (1) | Shaking (1) |

## *Clostridium tetani* UF toxoid

### *Equine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 10 | 9 | 1 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Injection site reaction (6) | Site reaction (swelling) (2) | Oedema (1) |
| Ataxia (2) | Agitation (1) | Pyrexia (1) |
| Lethargy (2) | Anorexia (1) | Sweating (1) |
| Pain (2) | Muscle stiffness (1) | |

## Clotrimazole

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Irritation (skin) (1)

## Cobalt EDTA

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Lack of effect (1)

## Contagious pustular dermatitis virus, living, cell culture

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 1 | 1 |

**Presenting signs (probable and possible)**

Lack of effect (2)

## *Corynebacterium pseudotuberculosis* (*C.ovis*) - toxoid

### *Caprine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 1 | 1 |

**Presenting signs (probable and possible)**

Injection site reaction (1)
Lack of effect (1)
Oedema (1)
Pain (1)

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 3 | 0 |

**Presenting signs (probable and possible)**

Injection site reaction (2)
Abscess (1)
Ataxia (1)
Death (1)
Shaking (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 2013 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

### Cyclosporin

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 87 | 56 | 31 |

**Presenting signs (probable and possible)**

Vomiting (55)
Diarrhoea (21)
Pruritis (16)
Lethargy (9)
Anorexia (8)
Tachypnoea (6)
Distress (4)
Hyperactivity (4)
Dermatitis (3)
Tremor (3)
Behavioural change (2)
Coat colour change (2)
Eczema (2)
Erythema (2)
Hyperkeratosis (2)
Injected mucous membranes (2)
Neoplasia (2)
Red eyes (2)
Vocalisation (2)
Abdominal pain (1)
Agitation (1)
Alopecia (1)
Cellulitis (1)
Collapse (1)
Dehydration (1)
Diabetes (1)
Elevated ALP (1)
Hairy (1)
Hepatopathy (1)
Lack of effect (1)
Leucocytosis (1)
Otitis externa (1)
Pancreatitis (1)
Pigmentation (1)
Restless (1)
Shaking (1)
Tachycardia (1)

## Cypermethrin

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 0 | 2 |

**Presenting signs (probable and possible)**

Lack of effect (2)

## Deltamethrin

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Lack of effect (1)

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 28 | 13 | 15 |

**Presenting signs (probable and possible)**

Lack of effect (8)
Pruritis (7)
Dermatitis (6)
Lethargy (3)
Irritation (skin) (2)
Agitation (1)
Anorexia (1)
Ataxia (1)
Dehydration (1)
Depression (1)
Electrolyte changes (1)
Facial oedema (1)
Listless (1)
Muscle twitching (1)
Rash (1)
Tremor (1)
Vomiting (1)

## Deoxycortone pivalate

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 2 | 0 |

**Presenting signs (probable and possible)**

Anorexia (1)
Injection site reaction (1)
Lethargy (1)
Pain (1)

## Deracoxib

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 0 | 2 |

**Presenting signs (probable and possible)**

Facial oedema (1)
Oedema (1)

## Dexamethasone 21-isonicotinate

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Blood in faeces (1)
Diarrhoea (1)

## Dexamethasone phenylpropionate

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Death (1)
Haemorrhagic gastroenteritis (1)
Lethargy (1)
Shock (1)

## Dexamethasone sodium phosphate

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Death (1)
Haemorrhagic gastroenteritis (1)
Lethargy (1)
Shock (1)

## Diazinon

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 0 | 3 |

**Presenting signs (probable and possible)**

Lack of effect (2)
Irritation (ear) (1)

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Paresis (1)

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Anorexia (1)
Ataxia (1)
Comatose (1)
Death (1)

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 0 | 2 |

**Presenting signs (probable and possible)**

Lack of effect (2)

## Dicyclanil

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 10 | 0 | 10 |

**Presenting signs (probable and possible)**

Lack of effect (10)

## Diflubenzuron

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 0 | 3 |

**Presenting signs (probable and possible)**

Lack of effect (3)

## Doramectin

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 1 | 2 |

**Presenting signs (probable and possible)**

Lack of effect (3)

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Ataxia (1)
Depression (1)
Lethargy (1)

## Emodepside

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 1 | 1 |

**Presenting signs (probable and possible)**

Alopecia (localised) (2)
Disorientation (1)
Pyoderma (1)
Vomiting (1)

## Enrofloxacin

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Vomiting (1)

## Equine herpes virus 1 (ehv-1) 438/77 strain

### *Equine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Injection site reaction (1)

## Equine herpes virus 4 (ehv-4) 405/76 strain

### *Equine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Injection site reaction (1)

## *Escherichia coli* k99 pilus antigens

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 2 | 0 |

**Presenting signs (probable and possible)**

Malaise (2)
Injection site reaction (1)
Milk production decrease (2)
Pyrexia (1)

## Eucalyptus oil

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Ataxia (1)
Seizure (1)
Muscle twitching (1)
Tremor (1)

## Febantel

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 0 | 3 |

**Presenting signs (probable and possible)**

Diarrhoea (2)
Anorexia (1)
Hyperactivity (1)
Tachycardia (1)
Vomiting (1)

## Feline calicivirus vaccines

Feline calicivirus is a constituent of 'core' feline vaccine products that targets common feline respiratory illness. Core vaccines protect animals from severe, life-threatening diseases with worldwide distribution.

The most commonly reported presenting signs include lethargy, anorexia, injection site reaction and pyrexia. 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 desired 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 feline calicivirus vaccine strains is low when compared with the number of doses sold in 2013 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

For more information about feline vaccines, go to the APVMA website at www.apvma.gov.au.

## Feline calicivirus

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 4 | 1 | 3 |

**Presenting signs (probable and possible)**

Pyrexia (2)
Ataxia (1)
Death (1)
Lame (1)
Lethargy (1)
Malaise (1)
Nystagmus (1)
Pain (1)
Pupillary light reflex (abnormal) (1)
Vomiting (1)
Weakness (1)

## Feline calicivirus - inactivated

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 53 | 34 | 19 |

**Presenting signs (probable and possible)**

Lethargy (22)
Injection site reaction (18)
Anorexia (17)
Pyrexia (17)
Vomiting (9)
Alopecia (localised) (5)
Diarrhoea (5)
Facial oedema (5)
Pruritis (5)
Pain (3)
Anaphylaxis (2)
Death (2)
Dehydration (2)
Erythema (2)
Hypersalivation (2)
Red eyes (2)
Swelling (local) (2)
Allergy (1)
Arthropathy (1)
Behavioural change (1)
Collapse (1)
Cyst (1)
Defaecation (1)
Depression (1)
Dermatitis (1)
Dyspnoea (1)
Eosinophilia (1)
Hyperactivity (1)
Irritation (skin) (1)
Lesions (1)
Muscle twitching (1)
Neutrophilia (1)
Oedema (1)
Pyoderma (1)
Sarcoma (1)
Shaking (1)
Tachycardia (1)
Tachypnoea (1)

## Feline calicivirus - live

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Anaphylactoid reaction (1)
Death (1)

## Feline *Chlamydia psittaci* - inactivated

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 4 | 3 | 1 |

**Presenting signs (probable and possible)**

Anorexia (2)
Anaphylaxis (1)
Arthropathy (1)
Death (1)
Erythema (1)
Injection site reaction (1)
Lethargy (1)
Pain (1)
Pruritis (1)
Pyrexia (1)

## Feline immunodeficiency virus (Petaluma strain) - inactive

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 8 | 2 | 6 |

**Presenting signs (probable and possible)**

Pyrexia (5)
Lethargy (3)
Anorexia (2)
Diarrhoea (2)
Pain (2)
Vomiting (2)
Anaphylactoid reaction (1)
Death (1)
Dehydration (1)
Hypothermia (1)
Injection site reaction (1)
Shaking (1)
Swelling (local) (1)
Tachycardia (1)

### Feline leukaemia virus - inactivated

#### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 7 | 2 | 5 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Pyrexia (5) | Alopecia (localised) (1) | Pruritis (1) |
| Anorexia (4) | Dehydration (1) | Shaking (1) |
| Lethargy (4) | Dermatitis (1) | Swelling (local) (1) |
| Injection site reaction (3) | Pain (1) | |

## Feline panleucopenia virus vaccines

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

The most commonly reported presenting signs include lethargy, injection site reaction, anorexia, and pyrexia. 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 desired 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 feline panleucopenia virus vaccine strains is low when compared with the number of doses sold in 2013 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

For more information about feline vaccines, go to the APVMA website at www.apvma.gov.au.

## Feline panleucopenia

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 4 | 1 | 3 |

**Presenting signs (probable and possible)**

- Pyrexia (2)
- Ataxia (1)
- Death (1)
- Lame (1)
- Lethargy (1)
- Malaise (1)
- Nystagmus (1)
- Pain (1)
- Pupillary light reflex (abnormal) (1)
- Vomiting (1)
- Weakness (1)

## Feline panleucopenia virus - inactivated

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 53 | 34 | 19 |

**Presenting signs (probable and possible)**

- Lethargy (22)
- Injection site reaction (18)
- Anorexia (17)
- Pyrexia (17)
- Vomiting (9)
- Alopecia (localised) (5)
- Diarrhoea (5)
- Facial oedema (5)
- Pruritis (5)
- Pain (3)
- Anaphylaxis (2)
- Death (2)
- Dehydration (2)
- Erythema (2)
- Hypersalivation (2)
- Red eyes (2)
- Swelling (local) (2)
- Allergy (1)
- Arthropathy (1)
- Behavioural change (1)
- Collapse (1)
- Cyst (1)
- Defaecation (1)
- Depression (1)
- Dermatitis (1)
- Dyspnoea (1)
- Eosinophilia (1)
- Hyperactivity (1)
- Irritation (skin) (1)
- Lesions (1)
- Muscle twitching (1)
- Neutrophilia (1)
- Oedema (1)
- Pyoderma (1)
- Sarcoma (1)
- Shaking (1)
- Tachycardia (1)
- Tachypnoea (1)

### Feline panleucopenia virus - live

#### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Anaphylactoid reaction (1) Death (1)

## Feline rhinotracheitis virus vaccine

Feline rhinotracheitis virus is a constituent of ‘core’ feline vaccine products that targets common feline respiratory illness. Core vaccines protect animals from severe, life-threatening diseases with worldwide distribution.

The most commonly reported presenting signs include 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. To protect from serious illnesses, a very large number of pets are vaccinated every year.

The number of reports associated with feline rhinotracheitis virus vaccine strains is low when compared with the number of doses sold in 2013 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

For more information about feline vaccines, go to the APVMA website at www.apvma.gov.au.

## Feline rhinotracheitis virus - inactivated

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 53 | 34 | 19 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Lethargy (22) | Erythema (2) | Eosinophilia (1) |
| Injection site reaction (18) | Hypersalivation (2) | Hyperactivity (1) |
| Anorexia (17) | Red eyes (2) | Irritation (skin) (1) |
| Pyrexia (17) | Swelling (local) (2) | Lesions (1) |
| Vomiting (9) | Allergy (1) | Muscle twitching (1) |
| Alopecia (localised) (5) | Arthropathy (1) | Neutrophilia (1) |
| Diarrhoea (5) | Behavioural change (1) | Oedema (1) |
| Facial oedema (5) | Collapse (1) | Pyoderma (1) |
| Pruritis (5) | Cyst (1) | Sarcoma (1) |
| Pain (3) | Defaecation (1) | Shaking (1) |
| Anaphylaxis (2) | Depression (1) | Tachycardia (1) |
| Death (2) | Dermatitis (1) | Tachypnoea (1) |
| Dehydration (2) | Dyspnoea (1) | |

## Fenbendazole

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

| | |
|---|---|
| Lethargy (1) | Vomiting (1) |

## Fenvalerate

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Lack of effect (1)

## Fipronil

Fipronil is a broad-spectrum phenyl pyrazole insecticide, which acts on the nervous system of insects following contact or ingestion. In veterinary situations, fipronil products are used as spray or concentrated spot-on formulations to control fleas, ticks and other ectoparasites that live on the skin of dogs and cats. Fipronil products are also used for the treatment and control of flea allergy dermatitis. These products have a very high volume of sales.

The most commonly reported presenting signs included pruritis, site reaction, erythema and localised alopecia.

Fipronil is currently under review by the APVMA's Chemical Review Program. Fipronil was nominated for review following the reporting of adverse experiences in humans and animals. The initial review considered concerns over toxicity primarily relating to skin irritation and induction of skin sensitisation, as well as concerns about the potential for fipronil to form toxic photodegradation products, its occupational health and safety issues, animal safety issues, and the adequacy of label instructions and warnings.

Updates on the progress of the review are available on the APVMA website: www.apvma.gov.au/products/review/current/fipronil.php

### Fipronil

#### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 61 | 10 | 51 |

**Presenting signs (probable and possible)**

Dermatitis (12)
Lack of effect (12)
Erythema (11)
Alopecia (localised) (9)
Pruritis (8)
Scabs (6)
Lethargy (5)
Lump (local) (3)
Alopecia (2)
Anorexia (2)
Inflammation (2)
Tremor (2)
Vomiting (2)
Ataxia (1)
Behavioural change (1)
Blisters (1)
Coat discoloration (1)
Crusting skin (1)
Diarrhoea (1)
Head tilt (1)
Irritation (skin) (1)
Muscle twitching (1)
Pain (1)
Welts (1)
Wheals (1)

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 38 | 19 | 19 |

**Presenting signs (probable and possible)**

Alopecia (localised) (22)
Scabs (8)
Erythema (6)
Pruritis (6)
Inflammation (4)
Lethargy (4)
Anorexia (3)
Alopecia (2)
Panting (2)
Vomiting (2)
Diarrhoea (1)
Head tilt (1)
Hypersalivation (1)
Lack of effect (1)
Lesions (1)
Tachycardia (1)
Tremor (1)

## Firocoxib

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 0 | 2 |

**Presenting signs (probable and possible)**

Lethargy (1)
Pancreatitis (1)
Renal failure (1)

## Fluazuron

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Lack of effect (1)

## Flunixin as Flunixin meglumine

### *Equine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 0 | 2 |

**Presenting signs (probable and possible)**

Ataxia (1)
Behavioural change (1)
Death (1)
Epistaxis (1)
Sweating (1)

## Fluoxetine hydrochloride

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 7 | 2 | 5 |

**Presenting signs (probable and possible)**

Anorexia (2)
Ataxia (2)
Behavioural change (2)
Elevated ALP (1)
Haematology (abnormal) (1)
Incoordination (1)
Lack of effect (1)
Somnolence (1)
Tremor (1)

## Formalin

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Anorexia (1)
Lethargy (1)

## Gentamicin sulfate

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 1 | 1 |

**Presenting signs (probable and possible)**

Irritation (eye) (1)
Irritation (skin) (1)

## Glucosamine hydrochloride

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 5 | 1 | 4 |

**Presenting signs (probable and possible)**

Vomiting (3)
Lethargy (2)
Diarrhoea (2)
Behavioural change (1)

## GNRF - protein conjugate

### *Equine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Pyrexia (1)

### *Porcine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 5 | 4 | 1 |

**Presenting signs (probable and possible)**

Anaphylaxis (2)
Death (1)
Lack of effect (1)
Mydriasis (1)
Tachycardia (1)
Tachypnoea (1)
Unconscious (1)

## Gonadotrophin-chorionic

### *Equine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Lack of effect (1)

## Imidacloprid

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 7 | 0 | 7 |

**Presenting signs (probable and possible)**

Lack of effect (5)
Hypersalivation (2)
Abdominal pain (1)
Ataxia (1)
Nausea (1)
Seizure (1)
Shaking (1)
Tachycardia (1)
Tachypnoea (1)
Vocalisation (1)

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 2 | 0 |

**Presenting signs (probable and possible)**

Erythema (1)
Frothing at the mouth (1)
Ulceration (1)

## Inactivated bovine pestivirus - Bega strain

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Lack of effect (1)

## Inactivated bovine pestivirus - Trangie strain

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Lack of effect (1)

## Inactivated rabbit calicivirus disease virus

### *Rabbit*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 23 | 11 | 12 |

**Presenting signs (probable and possible)**

Injection site reaction (9)
Alopecia (localised) (8)
Anorexia (6)
Lethargy (6)
Death (3)
Lame (3)
Pyrexia (2)
Site reaction (2)
Coat discoloration (1)
Inflammation (1)
Necrosis (1)
Oedema (1)
Skin slough (1)
Ulceration (1)

## Inactivated *Salmonella* Dublin & Typhimurium antigens

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Lack of effect (1)

## Insulin

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Pruritis (1)

## Iodine as Ethylenediamine dihydriodide

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Lack of effect (1)

## Isoflurane

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 5 | 0 | 5 |

**Presenting signs (probable and possible)**

Bradycardia (5)
Cardiac arrest (5)
Hypotension (5)
Respiratory problems (5)

## Isoleucine-L

### *Equine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 2 | 0 |

**Presenting signs (probable and possible)**

Anorexia (1)
Lethargy (1)
Pyrexia (1)
Shaking (1)
Tachycardia (1)

## Ivermectin

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Lack of effect (1)

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 4 | 0 | 4 |

**Presenting signs (probable and possible)**

Vomiting (4)
Diarrhoea (1)
Anorexia (1)
Lethargy (1)

### *Equine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Anorexia (1)
Scouring (1)

## *Leptospira borgpetersenii* serovar Hardjo

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 4 | 2 | 2 |

**Presenting signs (probable and possible)**

Allergy (1)
Anaphylaxis (1)
Death (1)
Lump (local) (1)
Milk production decrease (1)
Oedema (1)
Vaginitis (1)

## *Leptospira borgpetersenii* serovar Hardjo type Hardjobovi

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Death (1)
Lethargy (1)

## *Leptospira icterohaemorrhagiae* antigen

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 5 | 1 | 4 |

**Presenting signs (probable and possible)**

Vomiting (4)
Lethargy (3)
Facial oedema (1)
Injection site reaction (1)
Swelling (local) (1)

## *Leptospira interrogans* serovar Pomona

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 4 | 2 | 2 |

**Presenting signs (probable and possible)**

Allergy (1)
Anaphylaxis (1)
Death (1)
Lump (local) (1)
Milk production decrease (1)
Oedema (1)
Vaginitis (1)

## *Leptospira interrogans* serovar Pomona formol culture

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Death (1) Lethargy (1)

## Levamisole

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Wheals (1)

## Levamisole hydrochloride

### *Avian*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Death (1)

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Death (1) Tremor (1)

## Live feline herpes virus

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 5 | 1 | 4 |

**Presenting signs (probable and possible)**

Death (2)
Pyrexia (2)
Anaphylactoid reaction (1)
Ataxia (1)
Lame (1)
Lethargy (1)
Malaise (1)
Nystagmus (1)
Pain (1)
Pupillary light reflex (abnormal) (1)
Vomiting (1)
Weakness (1)

# Lufenuron

*Lufenuron* is a widely used systemic parasiticide that disrupts the development cycle of fleas. Lufenuron 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 vomiting and diarrhoea.

The number of reports associated with lufenuron is low when compared with the number of doses sold in 2013 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

## Lufenuron

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 82 | 40 | 42 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Vomiting (34) | Ataxia (2) | Oedema (1) |
| Diarrhoea (17) | Convulsions (2) | Polyuria (1) |
| Pruritis (11) | Erythema (2) | Rash (1) |
| Lethargy (10) | Flatulence (2) | Restless (1) |
| Lack of effect (5) | Seizure (2) | Self trauma (1) |
| Anorexia (4) | Behavioural change (1) | Shaking (1) |
| Urticaria (4) | Dermatitis (1) | Tremor (1) |
| Abdominal pain (3) | Eczema (1) | Urination (1) |
| Blood in faeces (3) | Facial oedema (1) | Welts (1) |
| Hyperactivity (3) | Hypersalivation (1) | |

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 4 | 0 | 4 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Lack of effect (3) | Injection site reaction (1) | Lump (local) (1) |

## *M. hyopneumoniae* - inactivated whole cell culture

### *Porcine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Death (1)
Respiratory problems (1)
Walking (difficult) (1)

## Maropitant as Maropitant citrate

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 4 | 0 | 4 |

**Presenting signs (probable and possible)**

Injection site reaction (3)
Lack of effect (1)
Oedema (1)
Pyrexia (1)

## Mavacoxib

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 20 | 10 | 10 |

**Presenting signs (probable and possible)**

Vomiting (11)
Anorexia (4)
Hepatopathy (3)
Azotaemia (2)
Haemorrhagic gastroenteritis (2)
Lethargy (2)
Renal failure (2)
Anaemia (1)
Arthropathy (1)
Blood in faeces (1)
Death (1)
Dehydration (1)
Diarrhoea (1)
Fatigue (1)
Gastric dilatation (1)
Gastroenteritis (1)
Haematemesis (1)
Hyperactivity (1)
Lack of effect (1)
Panting (1)
Renal disease (1)

## Medetomidine hydrochloride

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 6 | 0 | 6 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Bradycardia (3) | Death (1) | Seizure (1) |
| Anaphylactoid reaction (1) | Dyspnoea (1) | Shaking (1) |
| Apnoea (1) | Head tilt (1) | Somnolence (1) |
| Ataxia (1) | Nystagmus (1) | |

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 0 | 2 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Anisocoria (1) | Ataxia (1) | Death (1) |
| Anorexia (1) | Bradycardia (1) | |

## Meloxicam

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 5 | 0 | 5 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Death (2) | Abdominal pain (1) | Diarrhoea (1) |
| Renal failure (2) | Anaemia (1) | Lethargy (1) |
| Ulceration (stomach) (2) | Azotaemia (1) | Vomiting (1) |

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 0 | 3 |

**Presenting signs (probable and possible)**

Allergy (1)
Anorexia (1)
Dyspnoea (1)
Oedema (1)
Pulmonary oedema (1)
Renal failure (1)
Vomiting (1)

## Miconazole nitrate

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 1 | 1 |

**Presenting signs (probable and possible)**

Irritation (ear) (1)
Irritation (skin) (1)
Skin slough (1)
Swollen (ears) (1)

# Milbemycin oxime

*Milbemycin Oxime* is a widely used broad spectrum parasiticide that disrupts the invertebrate nervous system. 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 2013 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

## Milbemycin oxime

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 165 | 83 | 82 |

**Presenting signs (probable and possible)**

Vomiting (96)
Lethargy (29)
Diarrhoea (20)
Anorexia (15)
Pruritis (14)
Ataxia (8)
Hyperactivity (5)
Erythema (4)
Panting (4)
Seizure (4)
Urticaria (4)
Abdominal pain (3)
Blood in faeces (3)
Lack of effect (3)
Restless (3)
Shaking (3)
Convulsions (2)
Depression (2)
Flatulence (2)
Hypersalivation (2)
Somnolence (2)
Tremor (2)
Behavioural change (1)
Dermatitis (1)
Disorientation (1)
Eczema (1)
Facial oedema (1)
Frothing at the mouth (1)
Hepatopathy (1)
Hyperaesthesia (1)
Irritation (skin) (1)
Nausea (1)
Oedema (1)
Polyuria (1)
Prolapse (rectal) (1)
Prolapsed third eyelid (1)
Rash (1)
Self trauma (1)
Sneezing (1)
Stiffness (1)
Tachycardia (1)
Tachypnoea (1)
Urination (1)
Vocalisation (1)
Welts (1)

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 12 | 8 | 4 |

**Presenting signs (probable and possible)**

Vomiting (4)
Tremor (3)
Ataxia (2)
Lethargy (2)
Somnolence (2)
Alopecia (localised) (1)
Blindness (1)
Blurred vision (1)
Injection site reaction (1)
Lack of effect (1)
Shaking (1)

## Monensin as Monensin sodium

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 63 | 18 | 45 |

**Presenting signs (probable and possible)**

Regurgitation (31)
Lack of effect (22)
Choking (4)
Death (3)
Toxicity (2)
Anorexia (1)
Coat discoloration (1)
Diarrhoea (1)
Scouring (1)
Weight loss (1)

## Morantel tartrate

### *Equine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 1 | 1 |

**Presenting signs (probable and possible)**

Anorexia (1)
Gingival soreness (1)
Lethargy (1)
Pawing at ground (1)
Shaking (1)

## *Moraxella bovis*

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 9 | 5 | 4 |

**Presenting signs (probable and possible)**

Injection site reaction (5)
Lack of effect (4)

## Moxidectin

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Ataxia (1)

### *Equine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 1 | 2 |

**Presenting signs (probable and possible)**

Abdominal pain (1)
Anorexia (1)
Colic (1)
Colitis (1)
Lack of effect (1)
Lethargy (1)

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 2 | 0 |

**Presenting signs (probable and possible)**

Erythema (1)
Frothing at the mouth (1)
Ulceration (1)

## Moxidectin microspheres

*Moxidectin microspheres* act as 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 APVMA notes that products containing this active constituent are often used in conjunction with other products (including vaccines) resulting in a higher number of reports. In most cases it is impossible to attribute the cause of an adverse reaction to a single active constituent. Hence a single report may be classified against multiple active constituents that may have a potential relationship to an adverse experience.

The number of reports associated with moxidectin microspheres is low when compared with the number of doses sold in 2013 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

### Moxidectin microspheres

#### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 116 | 29 | 87 |

**Presenting signs (probable and possible)**

Vomiting (35)
Facial oedema (27)
Lethargy (15)
Injection site reaction (14)
Anaphylaxis (11)
Pruritis (11)
Anaphylactoid reaction (10)
Oedema (9)
Pyrexia (9)
Urticaria (9)
Anorexia (8)
Lump (local) (8)
Diarrhoea (7)
Pain (6)
Pale mucous membranes (5)
Allergy (4)
Ataxia (4)
Collapse (3)
Hypersalivation (3)
Cyanosis (2)
Erythema (2)
Hepatopathy (2)
Inflammation (2)
Tachypnoea (2)
Unconscious (2)
Abdominal pain (1)
Behavioural change (1)
Blood in faeces (1)
Bradycardia (1)
Conjunctivitis (1)
Convulsions (1)
Defaecation (1)
Epiphora (1)
Haemorrhage (1)
Hypotension (1)
Malaise (1)
Necrosis (1)
Panting (1)
Sarcoma (1)
Site reaction (swelling) (1)
Sweating (1)
Swelling (local) (1)
Tachycardia (1)
Tremor (1)
Wheals (1)

## *Mycobacterium paratuberculosis*

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Anaphylaxis (1)
Death (1)

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 1 | 1 |

**Presenting signs (probable and possible)**

Injection site reaction (1)
Lack of effect (1)

## *Mycoplasma hyopneumoniae* strain J

### *Porcine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 0 | 3 |

**Presenting signs (probable and possible)**

Vomiting (2)
Death (1)
Lethargy (1)

## Naphthalophos

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 12 | 4 | 8 |

**Presenting signs (probable and possible)**

Death (12)
Disorientation (1)
Muscle stiffness (1)
Convulsions (1)
Frothing at the mouth (1)
Weakness (1)

## Neomycin

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Anorexia (1)
Injection site reaction (1)
Lethargy (1)

## Neomycin as the sulfate

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 1 | 1 |

**Presenting signs (probable and possible)**

Site reaction (2)
Distress (1)

## Niclosamide monohydrate - micronised

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Collapse (1)
Head tilt (1)
Lethargy (1)
Tremor (1)

## Nitenpyram

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 1 | 1 |

**Presenting signs (probable and possible)**

Diarrhoea (1)
Lethargy (1)
Seizure (1)
Shaking (1)

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 19 | 17 | 2 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Hyperactivity (10) | Behavioural change (3) | Hypersalivation (1) |
| Tachypnoea (10) | Panting (3) | Mydriasis (1) |
| Pruritis (7) | Tachycardia (2) | Pyrexia (1) |
| Vocalisation (5) | Agitation (1) | Tremor (1) |
| Distress (4) | Ataxia (1) | |

## Nystatin

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 1 | 1 |

**Presenting signs (probable and possible)**

| | |
|---|---|
| Site reaction (2) | Distress (1) |

## Oestradiol

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Carcase damage (1)

## Oestradiol 17 beta

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Prolapse (1)

## Oestradiol benzoate

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Behavioural change (1)

## Oxantel embonate

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 0 | 3 |

**Presenting signs (probable and possible)**

Vomiting (2)
Anorexia (1)
Death (1)
Lack of effect (1)
Lethargy (1)

## Oxfendazole

### *Equine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Lack of effect (1)

## Oxibendazole

### *Equine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Anorexia (1)
Scouring (1)

## Oxyclozanide

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Death (1) Tremor (1)

## Oxytetracycline hydrochloride

### *Equine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Inflammation (1) Pain (1)

## Pantothenol-dl (panthenol-dl)

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Dyspnoea (1) Pulmonary oedema (1)

## Penethamate hydriodide

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Anaphylactoid reaction (1) Death (1)

## Pentobarbitone sodium

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Low efficacy (1)

## Pentosan polysulfate sodium

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 20 | 9 | 11 |

**Presenting signs (probable and possible)**

Vomiting (12)
Diarrhoea (2)
Lethargy (2)
Anaphylaxis (1)
Anorexia (1)
Ataxia (1)
Haematoma (1)
Injection site reaction (1)
Pain (1)
Panting (1)
Site reaction (swelling) (1)

### *Equine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 3 | 0 |

**Presenting signs (probable and possible)**

Anaphylaxis (1)
Death (1)
Injection site reaction (1)
Pyrexia (1)
Swelling (local) (1)

# Permethrin

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 at http://archive.apvma.gov.au/archive/community/2011-01_permethrin_cats.php

## Permethrin (25:75:cis:trans)

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

| | |
|---|---|
| Ataxia (1) | Seizure (1) |
| Muscle twitching (1) | Tremor (1) |

## Permethrin (40:60:cis:trans)

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 9 | 1 | 8 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Lack of effect (6) | Lethargy (1) | Tachycardia (1) |
| Hypersalivation (2) | Nausea (1) | Tachypnoea (1) |
| Abdominal pain (1) | Seizure (1) | Vocalisation (1) |
| Ataxia (1) | Shaking (1) | Vomiting (1) |
| Erythema (1) | Site reaction (1) | |

## Phenylalanine-d

### *Equine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 2 | 0 |

**Presenting signs (probable and possible)**

Anorexia (1)
Lethargy (1)
Pyrexia (1)
Shaking (1)
Tachycardia (1)

## Pimobendan

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Lethargy (1)
Tachycardia (1)

## Piperonyl butoxide

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 4 | 2 | 2 |

**Presenting signs (probable and possible)**

Tremor (3)
Muscle twitching (2)
Seizure (2)
Ataxia (1)
Frothing at the mouth (1)
Vomiting (1)

## Polymyxin b

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Anorexia (1)
Injection site reaction (1)
Lethargy (1)

## Polymyxin b sulfate

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 1 | 1 |

**Presenting signs (probable and possible)**

Irritation (ear) (1)
Irritation (skin) (1)
Skin slough (1)
Swollen (ears) (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.

The number of reports associated with praziquantel is low when compared with the number of doses sold in 2013 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

## Praziquantel

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 130 | 53 | 77 |

**Presenting sign (probable and possible)**

| | | |
|---|---|---|
| Vomiting (71) | Convulsions (2) | Panting (1) |
| Lethargy (25) | Flatulence (2) | Polyuria (1) |
| Diarrhoea (21) | Hypersalivation (2) | Prolapse (rectal) (1) |
| Anorexia (15) | Seizure (2) | Rash (1) |
| Pruritis (13) | Behavioural change (1) | Restless (1) |
| Hyperactivity (6) | Death (1) | Self trauma (1) |
| Ataxia (4) | Dermatitis (1) | Sneezing (1) |
| Urticaria (4) | Eczema (1) | Somnolence (1) |
| Abdominal pain (3) | Facial oedema (1) | Tachycardia (1) |
| Blood in faeces (3) | Frothing at the mouth (1) | Tachypnoea (1) |
| Erythema (3) | Hepatopathy (1) | Tremor (1) |
| Lack of effect (3) | Irritation (skin) (1) | Urination (1) |
| Shaking (3) | Oedema (1) | Welts (1) |

### *Equine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 4 | 1 | 3 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Anorexia (2) | Colitis (1) | Scouring (1) |
| Abdominal pain (1) | Lack of effect (1) | |
| Colic (1) | Lethargy (1) | |

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 14 | 9 | 5 |

**Presenting signs (probable and possible)**

Vomiting (5)
Alopecia (localised) (3)
Tremor (3)
Ataxia (2)
Lethargy (2)
Somnolence (2)
Blindness (1)
Blurred vision (1)
Disorientation (1)
Injection site reaction (1)
Lack of effect (1)
Pyoderma (1)
Shaking (1)

## Prednisolone acetate

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 1 | 1 |

**Presenting signs (probable and possible)**

Irritation (ear) (1)
Irritation (skin) (1)
Skin slough (1)
Swollen (ears) (1)

## Procaine penicillin

### *Equine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Death (1)

## Progesterone

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Behavioural change (1)

## Propentofylline

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 2 |

**Presenting signs (probable and possible)**

Diarrhoea (1)

## Propofol

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 0 | 2 |

**Presenting signs (probable and possible)**

Cardiac arrest (1)
Circulatory collapse (1)
Respiratory problems (1)
Tachycardia (1)

## Pyraclofos

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 0 | 3 |

**Presenting signs (probable and possible)**

Ovine Death (3)
Lethargy (2)
Anorexia (1)
Frothing at the nose (1)
Hypersalivation (1)
Recumbency (1)

## Pyrantel as pyrantel embonate

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 4 | 0 | 4 |

**Presenting signs (probable and possible)**

Diarrhoea (2)
Hyperactivity (1)
Vomiting (2)
Tachycardia (1)

## Pyrantel embonate

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 4 | 0 | 4 |

**Presenting signs (probable and possible)**

Vomiting (3)
Death (1)
Lack of effect (1)
Anorexia (2)
Diarrhoea (1)
Lethargy (1)

### *Equine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Lack of effect (1)

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Collapse (1)
Lethargy (1)
Head tilt (1)
Tremor (1)

## Pyrethrin

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 1 | 1 |

**Presenting signs (probable and possible)**

Frothing at the mouth (1)
Muscle twitching (1)
Seizure (1)
Tremor (1)

## Pyrethrins

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Tremor (1)
Vomiting (1)

## Quil

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Anaphylactoid reaction (1)
Death (1)

## Recombinant GP70 sub-type A

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Anaphylactoid reaction (1)
Death (1)

## Robenacoxib

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 6 | 3 | 3 |

**Presenting signs (probable and possible)**

Lethargy (4)
Dehydration (3)
Abdominal pain (2)
Haematemesis (2)
Anaemia (1)
Anorexia (1)
Diarrhoea (1)
Dizziness (1)
Hepatopathy (1)
Hypoproteinaemia (1)
Leucocytosis (1)
Neutrophilia (1)
Sedation (1)
Thrombocytopenia (1)
Vomiting (1)

# (S)-methoprene

(S)-methoprene is a pesticide that acts as a juvenile hormone mimic, disrupting the development of insects and preventing the larvae from emerging as adults. (S)-methoprene is used in conjunction with other active constituents.

The most commonly reported presenting signs included dermatitis, lack of effect and erythema.

The number of reports associated with (s)-methoprene is low when compared with the number of doses sold in 2013 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

## (S)-methoprene

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 58 | 10 | 48 |

**Presenting signs (probable and possible)**

- Dermatitis (12)
- Lack of effect (11)
- Erythema (10)
- Alopecia (localised) (9)
- Pruritis (7)
- Scabs (6)
- Lethargy (5)
- Lump (local) (3)
- Alopecia (2)
- Anorexia (2)
- Inflammation (2)
- Vomiting (2)
- Ataxia (1)
- Behavioural change (1)
- Blisters (1)
- Coat discoloration (1)
- Crusting skin (1)
- Diarrhoea (1)
- Head tilt (1)
- Irritation (skin) (1)
- Muscle twitching (1)
- Pain (1)
- Tremor (1)
- Welts (1)
- Wheals (1)

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 32 | 18 | 14 |

**Presenting signs (probable and possible)**

- Alopecia (localised) (21)
- Erythema (6)
- Pruritis (6)
- Scabs (6)
- Inflammation (4)
- Lethargy (3)
- Alopecia (2)
- Anorexia (2)
- Panting (2)
- Diarrhoea (1)
- Hypersalivation (1)
- Lesions (1)
- Tachycardia (1)
- Vomiting (1)

## Selamectin

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 15 | 8 | 7 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Alopecia (localised) (4) | Coughing (1) | Pigmentation (1) |
| Pruritis (4) | Erythema (1) | Self trauma (1) |
| Lethargy (2) | Hypersalivation (1) | Ulceration (1) |
| Site reaction (2) | Inflammation (1) | Urticaria (1) |
| Behavioural change (1) | Malaise (1) | Vomiting (1) |

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 66 | 58 | 8 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Alopecia (localised) (47) | Hypersalivation (2) | Lack of effect (1) |
| Site reaction (17) | Alopecia (1) | Mydriasis (1) |
| Inflammation (5) | Anorexia (1) | Pain (1) |
| Lethargy (4) | Coat discoloration (1) | Pruritis (1) |
| Vomiting (4) | Diarrhoea (1) | Pyoderma (1) |
| Dermatitis (3) | Erythema (1) | Self trauma (1) |
| Behavioural change (2) | Hyperactivity (1) | Site reaction (swelling) (1) |
| Burn(s) (2) | Irritation (skin) (1) | Stomatitis (1) |

## Selenium as sodium selenate

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 1 | 1 |

**Presenting signs (probable and possible)**

| | |
|---|---|
| Ataxia (1) | Lack of effect (1) |
| Death (1) | Shaking (1) |

## Selenium sulfide

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Erythema (1) Pruritis (1)

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 2 | 0 |

**Presenting signs (probable and possible)**

Halitosis (2) Anorexia (1) Lethargy (1)

Vomiting (2) Dyspnoea (1)

# Spinosad

Spinosad is an insecticidal chemical that disrupts the insect nervous system.

The most commonly reported presenting signs included vomiting, lethargy, lack of effect, anorexia, diarrhoea and depression.

The number of reports associated with spinosad has remained consistently high in the past three years. This matter was referred to the Veterinary Medicines Program for advice. It was considered in the majority of cases that the presenting sign accounting for most reports (ie vomiting) involved only a single instance from which the animal recovered very quickly. In light of this and the fact that the product label(s) contain warnings regarding expected reactions, no further action was considered necessary other than ongoing monitoring.

## Spinosad

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 793 | 607 | 186 |

**Presenting signs (probable and possible)**

Vomiting (643)
Lethargy (50)
Anorexia (24)
Diarrhoea (22)
Depression (21)
Lack of effect (17)
Seizure (12)
Pruritis (10)
Ataxia (9)
Malaise (9)
Shaking (8)
Nausea (7)
Panting (7)
Tremor (7)
Erythema (6)
Restless (6)
Behavioural change (5)
Somnolence (5)
Hypersalivation (4)
Hyperaesthesia (3)
Rash (3)
Urticaria (3)
Disorientation (2)
Frothing at the mouth (2)
Periorbital swelling (2)
Pyrexia (2)
Agitation (1)
Blood in faeces (1)
Coughing (1)
Distress (1)
Hives (1)
Hyperactivity (1)
Hypersensitivity reaction (1)
Irritation (skin) (1)
Lesions (1)
Prolapsed third eyelid (1)
Pupillary light reflex (abnormal) (1)
Red eyes (1)
Regurgitation (1)
Sedation (1)
Stiffness (1)
Tachycardia (1)
Unknown (1)
Vocalisation (1)
Weakness (1)
Welts (1)

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 48 | 6 | 42 |

**Presenting signs (probable and possible)**

Lack of effect (47)
Coat discoloration (1)
Flystrike (1)

## Stabilised green-lipped mussel powder

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 4 | 1 | 3 |

**Presenting signs (probable and possible)**

Lethargy (2)
Vomiting (2)
Behavioural change (1)
Diarrhoea (1)

## *Streptococcus equi* as cell free extract

### *Equine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 9 | 8 | 1 |

**Presenting signs (probable and possible)**

Injection site reaction (5)
Ataxia (2)
Lethargy (2)
Pain (2)
Site reaction (swelling) (2)
Agitation (1)
Anorexia (1)
Muscle stiffness (1)
Oedema (1)
Pyrexia (1)
Sweating (1)

## Sulfadoxine

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Injection site reaction (1)

## Temephos

### *Ovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Lack of effect (1)

## Tetrachlorvinphos

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Hypotension (1)

## Thiostrepton

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 1 | 1 |

**Presenting signs (probable and possible)**

Site reaction (2) Distress (1)

## Thyroxine sodium

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Lack of effect (1)

## Tiletamine as the hydrochloride

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Cardiac arrest (1)

## Toceranib

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 9 | 4 | 5 |

**Presenting signs (probable and possible)**

Lethargy (4)
Vomiting (3)
Anorexia (2)
Ataxia (2)
Epistaxis (2)
Seizure (2)
Shaking (2)
Blood in faeces (1)
Corneal oedema (1)
Death (1)
Haemorrhagic gastroenteritis (1)
Leucopenia (1)

## Trenbolone acetate

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Carcase damage (1)

## Triamcinolone acetonide

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 1 | 1 |

**Presenting signs (probable and possible)**

Site reaction (2) Distress (1)

## Triclabendazole

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Lack of effect (1)

## Triflumuron

### *Equine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 0 | 2 |

**Presenting signs (probable and possible)**

Alopecia (localised) (1) Crusting skin (1) Lesions (1)

## Trilostane - micronised

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 0 | 2 |

**Presenting signs (probable and possible)**

Malaise (1) Vomiting (1)

## Trimethoprim

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Injection site reaction (1)

## Tylosin tartrate

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Carcase damage (1)

## Vitamin B1 disulfide nitrate (thiamine disulphide nitrate)

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Dyspnoea (1) Pulmonary oedema (1)

## Vitamin B12a (hydroxocobalamin)

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Dyspnoea (1) Pulmonary oedema (1)

## Vitamin B2 phosphate sodium (riboflavin phosphate sodium)

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Feline Dyspnoea (1) Pulmonary oedema (1)

## Vitamin B3 (nicotinamide)

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Feline Dyspnoea (1) Pulmonary oedema (1)

## Vitamin B6 hydrochloride (pyridoxine hydrochloride)

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Feline Dyspnoea (1) Pulmonary oedema (1)

## Zeta-cypermethrin

### *Bovine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Agitation (1)
Irritation (skin) (1)

## Zolazepam as the hydrochloride

### *Feline*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Cardiac arrest (1)

# 4 VETERINARY MEDICINES—HUMAN ADVERSE EXPERIENCES

This chapter summarises classifications of APVMA assessments of adverse experience reports involving registered veterinary medicines and effects on humans in 2013.

The APVMA assessed and classified 3733 adverse experiences involving registered veterinary medicines in 2013. Adverse experiences in humans, for example, needle stick injuries, comprised 3% of these.

No regulatory action was required for active constituents involving veterinary medicines and human health in 2013.

See Chapter 2: *How to read this report* for more information on how to interpret data in this chapter correctly, and what data should *not* be used for.

## Adrenaline-l-acid tartrate-d

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Respiratory problems (1)

## Bupivacaine hydrochloride

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Respiratory problems (1)

## *Campylobacter fetus* (*Vibrio fetus*)

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 4 | 4 | 0 |

**Presenting signs (probable and possible)**

Needle stick injury (2)

Pain (1)

Swelling (local) (1)

## *Campylobacter fetus venerealis* biotype intermedius subt1

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 4 | 4 | 0 |

**Presenting signs (probable and possible)**

Needle stick injury (2) Pain (1) Swelling (local) (1)

## Cetrimide

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Respiratory problems (1)

## *Clostridium perfringens* type D toxoid

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 3 | 0 |

**Presenting signs (probable and possible)**

Site reaction (swelling) (2) Injection site reaction (1)

## *Clostridium tetani* - toxoid

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 3 | 0 |

**Presenting signs (probable and possible)**

Site reaction (swelling) (2) Injection site reaction (1)

## *Corynebacterium pseudotuberculosis* (*C.ovis*) - toxoid

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 3 | 0 |

**Presenting signs (probable and possible)**

Site reaction (swelling) (2)

Injection site reaction (1)

## Flumethrin

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 0 | 3 |

**Presenting signs (probable and possible)**

Erythema (1) Pruritis (1) Swelling (local) (1)

## Formalin

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 4 | 4 | 0 |

**Presenting signs (probable and possible)**

Needle stick injury (2) Pain (1) Swelling (local) (1)

## Imidacloprid

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 12 | 4 | 8 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Blisters (1) | Numbness (1) | Pruritis (1) |
| Burning sensation (1) | Paraesthesia (1) | Pustules (1) |
| Facial oedema (1) | Periorbital swelling (1) | Rash (1) |

## Lignocaine as Lignocaine hydrochloride

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Respiratory problems (1)

## Lufenuron

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Urticaria (1)

## Milbemycin oxime

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Urticaria (1)

## Moxidectin

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 5 | 3 | 2 |

**Presenting signs (probable and possible)**

Blisters (1)
Periorbital swelling (1)
Pruritis (1)
Rash (1)

## Permethrin (40:60:cis:trans)

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 5 | 1 | 4 |

**Presenting signs (probable and possible)**

Burning sensation (1)
Facial oedema (1)
Paraesthesia (1)
Pustules (1)
Rash (1)

## Praziquantel

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Urticaria (1)

## Propoxur

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 0 | 3 |

**Presenting signs (probable and possible)**

Erythema (1)
Pruritis (1)
Swelling (local) (1)

## Synthetic analogue of the Canine Appeasing Pheromone

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 0 | 2 |

**Presenting signs (probable and possible)**

Sore throat (1)

Swelling (local) (1)

## Tylosin as tartrate

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Rash (1)

# 5 AGRICULTURAL CHEMICALS—ANIMAL, PLANTS AND ENVIRONMENTAL SAFETY

This chapter summarises classifications of APVMA assessments in 2013 of adverse experience reports involving agricultural chemicals that were classified as ‘probable’ or ‘possible’.

Fifty adverse experience reports involving agricultural chemical products were classified in 2014. Of the 50 reports, 54 per cent involved effects on crops or animals, 36 per cent involved human health issues, and 10 per cent involved effects on the environment. Fourteen adverse experience reports involving agricultural chemical products were assessed and classified as either ‘probable’ or ‘possible’ in 2013.

No regulatory action was required for active constituents involving agricultural chemicals in 2013.

See Chapter 2: *How to read this report* for more information on how to interpret data in this chapter correctly, and what data should *not* be used for.

## 2,4-D

### *Home garden*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 0 | 2 |

**Presenting signs (probable and possible)**

Crop damage (2)

## Acetamiprid

### *Home garden*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Crop damage (1)

## Dicamba

### *Home garden*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 0 | 2 |

**Presenting signs (probable and possible)**

Crop damage (2)

## Mecoprop

### *Home garden*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 2 | 0 | 2 |

**Presenting signs (probable and possible)**

Crop damage (2)

## Paraquat present as Paraquat dichloride

### *Other*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Phytotoxicity (1)

## Piperonyl butoxide

### *Horticulture*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Crop damage (1)

## Pyrethrins

### *Horticulture*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 1 | 0 |

**Presenting signs (probable and possible)**

Crop damage (1)

## Sodium fluoroacetate (1080)

### *Canine*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 3 | 1 | 2 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Death (3) | Behavioural change (1) | Urination (1) |
| Frothing at the mouth (2) | Convulsions (1) | Vocalisation (1) |
| Vomiting (2) | Hyperactivity (1) | |

## Sulfometuron-methyl

### *Horticulture*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Crop damage (1)

# 6 AGRICULTURAL CHEMICALS—HUMAN ADVERSE EXPERIENCES

This chapter summarises classifications of APVMA assessments in 2013 of adverse experience reports involving agricultural chemicals and effects on humans.

The APVMA assessed and classified 50 adverse experience reports involving agricultural chemical products in 2013. Human health issues comprised 36 per cent of these.

No regulatory action was required for active constituents involving agricultural chemical products and human health in 2013.

See Chapter 2: *How to read this report* for more information on how to interpret data in this chapter correctly, and what data should *not* be used for.

## 2,4-D present as the dimethylamine and diethanolamine salts

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 5 | 5 | 0 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Burning sensation (1) | Headache (1) | Respiratory problems (1) |
| Dizziness (1) | Nausea (1) | |

## Bromoxynil present as the n-octanoyl ester

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 5 | 0 | 5 |

**Presenting signs (probable and possible)**

| | | |
|---|---|---|
| Abdominal pain (1) | Lethargy (1) | Vomiting (1) |
| Headache (1) | Nausea (1) | |

## Chlorpyrifos

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 5 | 0 | 5 |

**Presenting signs (probable and possible)**

Bronchitis (1)
Dizziness (1)
Lethargy (1)
Nasal discharge (1)
Sweating (1)

## Permethrin (25:75:cis:trans)

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Rash (1)

## Quizalofop-p-ethyl

### *Human*

| NUMBER OF REPORTS | PROBABLE | POSSIBLE |
|---|---|---|
| 1 | 0 | 1 |

**Presenting signs (probable and possible)**

Respiratory problems (1)

# 7 GLOSSARY

| | |
|---|---|
| Abscess | A collection of pus that has accumulated within a tissue |
| Alopecia | Absence of hair from areas where it is normally present |
| Anaphylactoid reaction | An anaphylactic-type reaction |
| Anaphylaxis/anaphylactic | An exaggerated allergic reaction of an animal to a foreign protein or other substances |
| Anorexia | Lack or loss of appetite |
| Anthelmintic | An agent destructive to worms |
| Ataxia | Unsteady walking action due to muscular incoordination |
| Bradycardia | Excessive slowness in the action of the heart |
| Cyanosis | Cyanosis is a physical sign causing bluish discoloration of the skin and mucous membranes due to a lack of oxygen in the blood |
| Dermatitis | Inflammation of the skin |
| Dyspnoea | Laboured breathing |
| Epistaxis | Bleeding from the nose |
| Erythema | Abnormal redness of the skin due to local congestion, as in inflammation |
| Fasciculation | Involuntary contractions or twitching of groups of muscle fibres |
| Haematemesis | Vomiting of blood |
| Haemorrhage | Bleeding |
| Hepatopathy | Disease or disorder of the liver |
| Hypersalivation | Excessive salivation |
| Hypersensitivity | An excessive reaction to an allergen |
| Melaena | The passage of dark faeces due to haemorrhage in the stomach or small intestine |
| Mydriasis | Unusual state of dilatation of pupil of the eye |
| Nausea | Unpleasant sensation in the stomach with a tendency to vomit |
| Necrosis | Pathological process associated with severe cellular trauma |
| Oedema | Abnormal accumulation of fluid in body cavities and under the skin |
| Paraesthesia | An abnormal sensation characterised by an unpleasant tingling sensation |
| Parasiticide | An agent that is destructive to parasites |

| | |
|---|---|
| Periorbital | Surrounding the eyes |
| Prolapse | To fall or slip out of place |
| Pruritis | Irritation and intense itching |
| Pyrexia | High fever |
| Registrant | The commercial party that is responsible for the marketing of the product |
| Seizure | A sudden attack, as of disease or epilepsy |
| Seroma | A collection of serum in the body, producing a tumor-like mass |
| Somnolence | State of sleepiness or unnatural drowsiness |
| Tachycardia | Excessive rapidity in the action of the heart |
| Tachypnoea | Rapid shallow breaths |
| Thrombocytopenia | Decrease in the number of blood platelets |
| Urticaria | Vascular reaction of the skin as a result of contact with a chemical or due to an immunological response |
| Wheals | A small swelling on the skin, as from an insect bite, that usually itches or burns |

# 8 INDEX OF ACTIVE CONSTITUENTS