Australian Government

Australian Pesticides and Veterinary Medicines Authority

REPORT OF ADVERSE EXPERIENCES

for Veterinary Medicines and Agricultural Chemicals

Calendar Year 2008

SEPTEMBER 2009

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This document is published by the APVMA. In referencing this document the APVMA should be cited as both author and publisher.

ISBN: [Enter ISBN Number if required (consult with Information Services) or delete if not required]

Website: This publication is available from the APVMA website: http://www.apvma.gov.au

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EXECUTIVE SUMMARY

The Adverse Experience Reporting Program for veterinary medicines (AERP *Vet*) and the AERP for agricultural chemicals (AERP *Ag*) are quality assurance programs that facilitate the management of veterinary medicines and agricultural chemicals throughout their lifecycle, from registration to end product user.

This report contains information on adverse experience reports for veterinary medicines (Chapter 2 and 3) and agricultural chemicals (Chapter 4 and 5). This report is also available online from the APVMA website at www.apvma.gov.au.

AERP *Vet* - During the 2008 calendar year a total of 1712 adverse experience reports were classified by the APVMA. Of these, 1079 were classified as '*probable' or ' possible'.* These included 839 *standard* animal reports and 9 *human* reports and 231 reports relating to '*lack of efficacy'*. The adverse experience reports in animals were submitted by veterinary surgeons, pet owners, farmers, members of the public and product registrants.

AERP *Ag* - During the 2008 calendar year a total of 123 adverse experience reports were classified by the APVMA. Of these, 24 reports were classified as '*probable*' or '*possible*'. These included 2 *human* reports, 15 *environmental* reports and 4 *standard* crop or animal ..reports. There were 3 reports relating to '*lack of efficacy*'. In addition, numerous enquiries about Agvet chemicals were received from members of the public.

The quality of the information provided in the reports was generally of a high standard, which in part reflects the good interaction between the APVMA, the veterinary profession, the agricultural community and registrants.

Off-label incidents are not included in this report. However, it is valuable to report off-label adverse experiences as these can cover very serious incidents. For example:

- Poor anaesthetic treatment protocols have resulted in delayed recovery or death of animals, with some instances of treatment protocols clearly contradicting the label.
- Concurrent use of medications, particularly non-steroidal anti-inflammatory drugs, continues to result in a variety of veterinary adverse experience reports.
- The use of dog products on cats has caused serious injury to cats. This action is clearly off-label and the public should be aware that some ingredients are toxic to cats and that dose rates are significantly different between the two species.
- There were a total of 104 human reports received in 2008 across AERP *Ag* and *Vet*. The reports were classified as follows : 11 '*probable or possible*', 60 '*off-label*', and 33 '*unlikely or unknown*'. 57 percent were related to off-label product use, including needle stick injuries, which continue to cause concern. Individuals involved in animal husbandry should take appropriate preventative action when injecting animals.

Throughout 2008 a number of risk management strategies aimed at mitigating and minimising the number of adverse events were actioned.

These included:

- Proactive management of issues associated with permethrin toxicity in cats

Other activities undertaken by the AERP during 2008 included:

- Encouraging reporting through networks of the members of APVMA's Community Consultative Committee (CCC)
- Raising awareness of the AERP program in the wider community through presentations and advertising.
- Promoting AERP and displaying the AERP banner at the Australian Veterinary Association (AVA) Conference in Perth in May 2008.
- Publishing an AERP article and advertising the AERP banner in the Farm Guide Magazine 2008.

1 INTRODUCTION

1.1 Program outline

The APVMA is the Australian government authority which manages the National Registration Scheme for Agricultural and Veterinary Chemicals. It is responsible for the assessment, evaluation and registration (marketing authorisation) of pesticides and veterinary medicines prior to sale, and their regulation up to and including the point of retail sale. The APVMA also manages quality assurance programs that monitor the safety and performance of registered products.

'Veterinary Medicines' include 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 both companion and production animals.

'Pesticides' and 'Agricultural Chemicals' include 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 Adverse Experience Reporting Program (AERP) is a post-registration quality assurance program established by the APVMA to help facilitate the management of veterinary medicines and agricultural chemicals throughout their lifecycle. The program provides a means of identifying corrective action that may be necessary to assure the continued safety, quality and effectiveness of registered products. Recording and investigating reports of adverse experiences is an important step in detecting unusual or rare conditions that were not evident in clinical or field trials and, as a result, could not be assessed during the product registration process. The AERP helps to ensure that products on the market:

- remain safe, effective and of acceptable quality
- are used in the best possible way
- include instructions and warnings on the label that are appropriate.

1.2 What is an adverse experience?

The APVMA defines an ***AERP Vet adverse experience*** as:

An unintended or unexpected (deleterious) effect on animals, human beings or the environment, including injury, sensitivity reactions or lack of efficacy associated with the clinical use of a veterinary chemical product when used according to label instructions.

A number of veterinary medicines have known side effects when used as directed and it is useful to maintain a record of these to be able to assess their true incidence. Furthermore, because of the enormous diversity amongst animal species and the relatively small number of veterinary medicines in the marketplace, it is occasionally necessary to use products in circumstances where there is limited information available on the dose rates or adverse reactions in off-label species. Such products may have originally been intended for

use in humans or other animal species. For this reason it is important that all adverse experiences, whether associated with recommended label use or not, are reported.

The APVMA defines an ***AERP Ag adverse experience*** as:

An unintended or unexpected effect (deleterious) on plants, plant products, animals, human beings or the environment, including injury, sensitivity reactions or lack of efficacy associated with the use of an agricultural chemical product when used according to label directions.

It is possible that some agricultural chemicals may cause effects when used according to the label and it is useful to maintain a record so that the true incidence of any unwanted effects can be assessed. Thus it is important to report all adverse experiences.

Adverse Experiences - Serious and Minor

The APVMA defines a ***serious adverse experience*** as one that involves:

- widespread and significant crop and plant damage (eg. crop death, severe stunting or significant yield loss)
- life-threatening or other significant effects in a human, including death
- farm, domestic and native animal deaths or
- significant environmental damage, including fish kills and water quality issues.

The APVMA defines a ***minor adverse experience*** as one that involves:

- crop and plant damage that is not widespread or significant (e.g. minor wilting or yellowing of crops, minor yield loss)
- human health effects that require medical attention, but are not life-threatening
- injury to domestic and native animals that require veterinary attention or
- minor environmental damage.

1.3 Who can report an adverse experience?

Anyone can submit an adverse experience report for a Veterinary Medicine or Agricultural Chemical. The APVMA encourages voluntary reporting, particularly from veterinarians, animal owners, farmers, gardeners, agronomists, health workers, bystanders, state and territory authorities and other users of veterinary medicines and agricultural chemicals.

Registrants of veterinary medicines and agricultural chemicals also have a legal obligation to report to the AERP. 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 adverse experience information on human health issues, harm to animals, damage to plants, property or the environment, or lack of efficacy when the

products are used according to label directions. The registrant reporting component of AERP *Ag* is one method by which registrants can meet certain legislative obligations of Section 161 of the *Agvet Code*.

1.4 How to report an adverse experience?

Adverse experiences can be reported online at https://services.apvma.gov.au/AerpWebApp/ or by using the Adverse Experience Reporting Form, or by contacting the AERP directly (contact details are on page 9).

1.5 Benefits of the AERP

The AER Program provides numerous benefits to a wide range of stakeholders.

Benefits to the community

- helps ensure the safety and efficacy of registered products in the marketplace
- provides confidence in the regulatory system.
- provides up-to-date safety information on registered products
- ensures that the latest safety information is available on product labels
- provides information on modifications needed to work practices to ensure safe use of chemicals
- identifies and acts on emerging issues quickly.

Benefits to States and Territories

- provides a format for communication of issues that cross over jurisdictional boundaries.

1.6 Evaluation of adverse experience reports

Reports received by the APVMA are assessed to determine whether the adverse experience is related to the use of, or exposure to, the product.

Procedures for dealing with adverse experience reports are as follows:

- Reports made directly to the APVMA (voluntary reports) are copied to the product registrant for investigation. The registrant may then contact either the reporting person or the attending veterinarian and discuss the matter to determine if any follow up laboratory, pathology or other veterinary work is required.
- The product registrant subsequently provides the APVMA with an investigation report into the incident. The APVMA assesses this information and determines whether any further investigative work is required. In some cases, additional expert opinion may be sought from relevant State or Territory government agencies like the Office of Chemical Safety and Environmental Health (OCSEH), the Department of the Environment, Water, Heritage and the Arts (DEWHA), universities, the Australian Veterinary Association, or other appropriate authorities.

- The APVMA will also consider published scientific information or information provided by an equivalent international organisation.
- In all cases a standard method of assessment is used to determine whether the adverse experience may have been related to the use of the veterinary medicine or agricultural chemical (i.e. 'classification'; see 1.7 below). The APVMA also considers whether the product was used according to the label directions.
- The person submitting making the report will be advised of the outcome of the investigations.
- If a report of an adverse experience is made directly to the product registrant, they will provide a report to the APVMA (Registrant report). The APVMA will then assess this information and determine whether any further investigative or regulatory action is required.

1.7 Classification of adverse experience reports

The relationship between the use of a product and the reported clinical signs is determined after the incident has been investigated. This relationship is expressed in terms of ***probable*, *possible*, *probable or possible off-label*, *unlikely* and *unknown*.**

Probable

For inclusion in the category *probable,* all of the following minimum criteria should be met:

- there should be a reasonable association between the administration of the product and onset and duration of the reported adverse experience,
- the description of the clinical signs should be consistent with or at least plausible given the known pharmacology and toxicology of the product, and
- there should be no other equally plausible explanation (or contributing factors) for the clinical signs.

When any of the above criteria cannot be satisfied (due to lack of sufficient information or conflicting data) then the association cannot be assessed as *probable*.

Possible

For inclusion in the category *possible,* association of the adverse experience with administration of the primary suspect product is one of other possible and equally plausible explanations (or contributing factors) for the described adverse experience.

Probable or Possible Off-label

This is as per the classification of *probable* or *possible* but where there is obvious evidence of off-label use (including use in species not listed on the product label, over-dosing or under-dosing). It is acknowledged that depending on State and Territory legislation and veterinary prescribing privileges, APVMA permits and other legal exemptions may allow off-label use in some situations.

Unlikely

Where sufficient information exists to establish that the described adverse experience was not likely to have been associated with administration or use of the product(s), or other more plausible explanations exist, the assessment should be categorised as *unlikely*.

Unknown

All adverse experiences for which reliable data are either unavailable or are insufficient to make an assessment should be categorised as *unknown*.

1.8 Corrective action determination

The APVMA takes into account a broad range of issues and options when deciding what, if any, corrective action is required to mitigate possible risks to humans, animals, or the environment.

For each registered veterinary medicine, and more broadly for each active constituent, the APVMA conducts a trend analysis of all adverse experience reports received. All reports that have been classified as probable or possible are compared to 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]. This report also recommends that if the reporting incidence is greater than one per 10,000 in two out of three consecutive years or an exceptional incidence of three or more per 10,000 occurs on any one occasion, or a consistent rising trend is seen over five years (irrespective of the reporting incidence), then action may be taken.

The APVMA considers other scientific literature and information relating to trend analysis and risk assessment when determining whether corrective action is required. The APVMA also takes into account whether the noted clinical signs are listed in warning statements on the product label, in which case a slightly higher reporting incidence may be acceptable, and also considers the severity of clinical signs (i.e. more severe signs may trigger corrective action at a lower reporting incidence).

1.9 Outcomes of the program

Based on the assessment of adverse experience reports certain risk mitigation strategies or corrective actions may be requested. These may include, but are not restricted to, the following:

- registration amendments, such as label changes, changes to the method of manufacture or the product's physical or chemical design, changes to container design, changes to production line processes, or suspension and/or cancellation of registration and approval

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

- review of the active constituent under the APVMA's Chemical Review Program
- referral for action, such as compliance action, including product and batch recalls, referral to state authorities for action, or nomination of products or active constituents for formal chemical review by the APVMA, (note that once the recommendation for review has been made by the AERP the review program will conduct consultation and scoping prior to determining whether a review is necessary or not)
- education and publicity, such as providing scientific papers or articles on issues identified for relevant journals, magazines or newspapers. When required education can be directed toward veterinary profession, farming community or wider public on issues relating to use of products.

The conclusions drawn by the APVMA during the investigation and evaluation of each adverse experience report will be provided to the reporting person. This will include an explanation of whether the APVMA considers that the observed adverse effects (including health symptoms) were related to the use of or exposure to the product. The APVMA will explain what these conclusions are and what corrective action, if any, needs to be taken in response to the information.

The information contained in this report is only a general reference to the type of adverse experiences that have been reported either to the APVMA or to product registrants. This report does not provide any correlation between the number of units of each product sold and the number of adverse experiences for each product reported. It must also be noted that each product may have more than one active constituent and hence the adverse experience reported may be related to any one or more of the active constituents present in the particular product reported to the AERP.

Therefore this information should not be used for:

- associating adverse effects with a particular product or active constituent
- assessing the safety and efficacy of a product or active constituent
- establishing acceptable frequency of occurrence of an adverse experience, or
- comparing one product or active constituent with another product or active constituent.

1.10 Report Structure

This report is arranged into the following sections:

Chapters 2 and 3 AERP *Vet*

- Chapter 2 is a summary of adverse experience reports other than human health (including farm, domestic and native animals, environmental damage and lack of efficacy) listed by active constituent.
- Chapter 3 is a summary of adverse experience reports involving human health.

Chapters 4 and 5 AERP *Ag*

- Chapter 4 is a summary of adverse experience reports other than human health (including crop damage, environmental damage and lack of efficacy) listed by active constituent.
- Chapter 5 is a summary of adverse experience reports involving human health.

The reports presented in the Tables below are for each '***active constituent***' and are classified as '***probable***' and '***possible***'. The information for each active is divided into '***species affected***'. Several species tables may be present for each active constituent. For effects on humans the reports are presented in Tables 3.2 and 5.2. Multiple '***presenting signs***' may be present for any one report, these are listed under '***incidence***' in the second table.

ACTIVE CONSTITUENT

Species Affected

NUMBER OF REPORTS	PROBABLE	POSSIBLE
X+Y	X	Y

PRESENTING SIGN	INCIDENCE
Burn(s)	A
Scabs	B
Skin slough	C

1.11 For further information

For information about the Adverse Experience Reporting Program please contact:

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Fax: +61 2 6210 4813
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2 VETERINARY - SUMMARY OF ADVERSE EXPERIENCE REPORTS 2008 (ANIMAL)

2.1 Adverse experience report summaries for each species listed by active constituent

Active constituent name

- Each active constituent is listed alphabetically, with a summary of the adverse experience reports.
- It is important to note that the number of adverse experience reports and the presenting signs observed may be listed under more than one active constituent if they refer to a product that contains multiple active constituents.

The species

- For each active constituent, the adverse experience reports are listed by species in alphabetical order.

Number of reports

- Only adverse experience reports that were classified by the APVMA during the calendar year 2008 as being either probable or possible have been included in these lists. The summary table indicates how many reports were classified as probable and how many were classified as possible.

Presenting signs

- All observed clinical signs for reports that were classified as probable and possible are listed in order of frequency.
- It is important to note that multiple clinical signs have been noted in some individual reports. Therefore the list of clinical signs observed does not relate directly to the total number of reports received.

Summary of corrective action

- No regulatory action was required for many of the active constituents as the frequency of adverse experience reports received was relatively low when compared with the total number of doses sold. A short narrative is provided on any corrective action taken as a result of assessment of the adverse experience information for an active constituent.
- In many instances, the potential for adverse reactions to many veterinary medicines was recognised at the time of product registration. When adverse experiences are reported for such medicines, the need for corrective action is considered against the data assessed at the time of product registration.

2.2 Veterinary – standard AERs

ABAMECTIN

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Lack of effect	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

ACEPROMAZINE MALEATE

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Death	1
Respiratory problems	1
Sedation (prolonged)	1

ALBENDAZOLE

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

PRESENTING SIGN	INCIDENCE
Lack of effect	3

ALPHA AMYLASE

Porcine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Residue violation	1

ALPHA-CYPERMETHRIN

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

PRESENTING SIGN	INCIDENCE
Lack of effect	3

ALPHAXALONE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	2	2

PRESENTING SIGN	INCIDENCE
Apnoea	1
Cyanosis	2
Diarrhoea	1
Recovery (poor)	1
Seizure	1
Vomiting	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
11	2	9

PRESENTING SIGN	INCIDENCE
Death	2
Swelling (local)	2
Swollen (ears)	2
Swollen feet	2
Apnoea	1
Ataxia	1
Behavioural change	1
Cardiac arrest	1
Coughing	1
Cyanosis	1
Erythema	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1
Lame	1
Opisthotonos	1
Pain	1
Respiratory problems	1
Seizure	1

ALUMINIUM HYDROXIDE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
22	7	15

PRESENTING SIGN	INCIDENCE
Abscess	2
Injection site reaction	14
Lump (local)	8
Pain	4
Pyrexia	3
Lethargy	2
Anorexia	1
Collapse	1
Depression	1
Epistaxis	1
Facial oedema	1
Immune-mediated haemolytic anaemia	1
Leucopenia	1
Muscle stiffness	1

PRESENTING SIGN	INCIDENCE
Oedema	1
Polyarthritis	1
Site reaction	1
Thrombocytopenia	1
Vomiting	1

AMITRAZ

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Bloat	1
Death	1
Lethargy	1

AMOXYCILLIN AS AMOXYCILLIN TRIHYDRATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Injection site reaction	2
Abscess	1
Lump (local)	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Injection site reaction	1

ANAPLASMA CENTRALE

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
10	0	10

PRESENTING SIGN	INCIDENCE
Lack of effect	8
Death	2
Vaccination reaction	1

BABESIA BIGEMINA

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
10	0	10

PRESENTING SIGN	INCIDENCE
Lack of effect	8
Death	2
Vaccination reaction	1

BABESIA BOVIS

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
10	0	10

PRESENTING SIGN	INCIDENCE
Lack of effect	8
Death	2
Vaccination reaction	1

BENAZEPRIL HYDROCHLORIDE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lethargy	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Vomiting	1

BENZATHINE PENICILLIN

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

PRESENTING SIGN	INCIDENCE
Death	2
Ataxia	1
Stiffness	1

BETA GLUCANASE

Porcine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Residue violation	1

BETAMETHASONE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

PRESENTING SIGN	INCIDENCE
Deafness	3

BORDETELLA BRONCHISEPTICA

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
28	2	26

PRESENTING SIGN	INCIDENCE
Coughing	12
Vomiting	7
Anorexia	5
Lethargy	4
Depression	2
Pain	2
Periorbital swelling	2
Pyrexia	2
Sneezing	2
Vocalisation	2
Agitation	1
Alopecia (localised)	1
Anaphylaxis	1
Facial oedema	1
Frothing at the mouth	1
Haemorrhagic gastroenteritis	1
Injection site reaction	1
Lump (local)	1
Malaise	1
Nasal discharge	1
Respiratory problems	1
Tremor	1

PRESENTING SIGN	INCIDENCE
Urticaria	1

BORDETELLA BRONCHISEPTICA (INACTIVATED CELL FREE EXTRACT)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
108	62	46

PRESENTING SIGN	INCIDENCE
Lethargy	46
Pain	36
Vomiting	22
Injection site reaction	21
Anorexia	19
Facial oedema	19
Shaking	12
Pyrexia	9
Lump (local)	8
Urticaria	8
Collapse	4
Depression	4
Erythema	4
Pale mucous membranes	4
Pruritis	4
Swollen lips and face	3
Abscess	2
Ataxia	2
Disorientation	2

PRESENTING SIGN	INCIDENCE
Restless	2
Site reaction	2
Thrombocytopenia	2
Weakness	2
Wheals	2
Anaphylactoid reaction	1
Anaphylaxis	1
Bradycardia	1
Coughing	1
Diarrhoea	1
Distress	1
Dyspnoea	1
Epistaxis	1
Hives	1
Hypersalivation	1
Hypotension	1
Immune-mediated haemolytic anaemia	1
Incontinence	1
Leucopenia	1
Malaise	1
Muscle stiffness	1
Oedema	1
Polyarthritis	1
Pupillary light reflex (abnormal)	1
Site reaction (swelling)	1
Tachypnoea	1
Unconscious	1

PRESENTING SIGN	INCIDENCE
Urination	1

The most reported side effects of vaccinations include vomiting, coughing, lethargy and diarrhoea. These occur very occasionally with most vaccines.

Due to the low number of reports when taking into consideration the large number of dogs vaccinated each year, no further regulatory action is required other than continuing monitoring for future adverse experience reports.

BORDETELLA BRONCHISEPTICA KILLED VACCINE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	0	6

PRESENTING SIGN	INCIDENCE
Allergy	3
Diarrhoea	3
Facial oedema	3
Vomiting	3

The most reported side effects of vaccinations include vomiting, coughing, lethargy and diarrhoea. These occur very occasionally with most vaccines.

Due to the low number of reports when taking into consideration the large number of dogs vaccinated each year, no further regulatory action is required other than continuing monitoring for future adverse experience reorts.

BORIC ACID

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	0	6

PRESENTING SIGN	INCIDENCE
Irritation (skin)	1

CALCIUM PENTOSAN POLYSULFATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Collapse	1
Death	1

CAMPYLOBACTER FELIS (VIBRO FETUS) VENEREALIS BIOTYPE 1

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

PRESENTING SIGN	INCIDENCE
Injection site reaction	2
Anorexia	1
Oedema	1

CANINE ADENOVIRUS TYPE 2

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
100	54	46

PRESENTING SIGN	INCIDENCE
Lethargy	44
Pain	31
Vomiting	26
Facial oedema	21

PRESENTING SIGN	INCIDENCE
Anorexia	19
Shaking	14
Injection site reaction	8
Urticaria	8
Pyrexia	7
Coughing	4
Depression	4
Diarrhoea	4
Erythema	4
Pale mucous membranes	4
Pruritis	4
Allergy	3
Collapse	3
Swollen lips and face	3
Weakness	3
Anaphylaxis	2
Ataxia	2
Disorientation	2
Frothing at the mouth	2
Restless	2
Tremor	2
Wheals	2
Bradycardia	1
Distress	1
Dyspnoea	1
Haemorrhagic gastroenteritis	1
Hives	1

PRESENTING SIGN	INCIDENCE
Hypersalivation	1
Hypotension	1
Lack of effect	1
Lump (local)	1
Malaise	1
Paresis	1
Pupillary light reflex (abnormal)	1
Site reaction	1
Site reaction (swelling)	1
Sneezing	1
Tachypnoea	1
Thrombocytopenia	1
Unconscious	1
Urination	1

The most reported side effects of vaccinations include vomiting, coughing, lethargy and diarrhoea. These occur very occasionally with most vaccines.

Due to the low number of reports when taking into consideration the large number of dogs vaccinated each year, no further regulatory action is required other than continuing monitoring for future adverse experience reports.

CANINE ADENO VIRUS TYPE 2 – LIVE (INFECTIOUS HEPATITIS)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
16	5	11

PRESENTING SIGN	INCIDENCE
Injection site reaction	8
Lump (local)	6
Lethargy	3
Pain	3
Anorexia	2
Collapse	1
Epistaxis	1
Facial oedema	1
Immune-mediated haemolytic anaemia	1
Polyarthritis	1
Pyrexia	1
Thrombocytopenia	1

CANINE ADENOVIRUS TYPE 2 LIVE (CAV II)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	1	3

PRESENTING SIGN	INCIDENCE
Anaphylactoid reaction	1
Injection site reaction	1
Lethargy	2
Vomiting	1

The most reported side effects of vaccinations include vomiting, coughing, lethargy and diarrhoea. These occur very occasionally with most vaccines.

Due to the low number of reports when taking into consideration the large number of dogs vaccinated each year, no further regulatory action is required other than continuing monitoring for future adverse experience reports.

CANINE ADENOVIRUS TYPE 2 STRAIN MANHATTAN - LIVE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
14	2	12

PRESENTING SIGN	INCIDENCE
Injection site reaction	5
Vomiting	5
Pain	3
Pyrexia	3
Abscess	2
Anorexia	2
Depression	2
Lump (local)	2
Periorbital swelling	2
Vocalisation	2
Agitation	1
Alopecia (localised)	1
Lethargy	1
Leucopenia	1
Malaise	1
Muscle stiffness	1
Oedema	1
Site reaction	1

PRESENTING SIGN	INCIDENCE
Tremor	1
Urticaria	1

CANINE DISTEMPER

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

CANINE DISTEMPER VIRUS

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
19	2	17

PRESENTING SIGN	INCIDENCE
Lethargy	6
Vomiting	6
Facial oedema	4
Pyrexia	4
Allergy	3
Anorexia	3
Diarrhoea	3
Restless	2
Anaphylaxis	1
Ataxia	1
Coughing	1

PRESENTING SIGN	INCIDENCE
Depression	1
Frothing at the mouth	1
Haemorrhagic gastroenteritis	1
Injection site reaction	1
Lack of effect	1
Lump (local)	1
Pain	1
Paresis	1
Pupillary light reflex (abnormal)	1
Weakness	1

CANINE DISTEMPER VIRUS - LIVING

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
99	58	41

PRESENTING SIGN	INCIDENCE
Lethargy	43
Pain	33
Vomiting	21
Anorexia	18
Facial oedema	18
Injection site reaction	16
Shaking	14
Urticaria	8
Lump (local)	6
Collapse	4

PRESENTING SIGN	INCIDENCE
Erythema	4
Pale mucous membranes	4
Pruritis	4
Pyrexia	4
Depression	3
Swollen lips and face	3
Disorientation	2
Thrombocytopenia	2
Tremor	2
Weakness	2
Wheals	2
Anaphylactoid reaction	1
Anaphylaxis	1
Ataxia	1
Bradycardia	1
Coughing	1
Diarrhoea	1
Distress	1
Dyspnoea	1
Epistaxis	1
Hives	1
Hypersalivation	1
Hypotension	1
Immune-mediated haemolytic anaemia	1
Malaise	1
Polyarthritis	1
Site reaction	1

PRESENTING SIGN	INCIDENCE
Site reaction (swelling)	1
Tachypnoea	1
Unconscious	1
Urination	1

The most reported side effects of vaccinations include vomiting, coughing, lethargy and diarrhoea. These occur very occasionally with most vaccines.

Due to the low number of reports when taking into consideration the large number of dogs vaccinated each year, no further regulatory action is required other than continuing monitoring for future adverse experience reports.

CANINE DISTEMPER VIRUS STRAIN ONDERSTEPOORT

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
14	2	12

PRESENTING SIGN	INCIDENCE
Injection site reaction	5
Vomiting	5
Pain	3
Pyrexia	3
Abscess	2
Anorexia	2
Depression	2
Lump (local)	2
Periorbital swelling	2
Vocalisation	2
Agitation	1
Alopecia (localised)	1

Lethargy	1
Leucopenia	1
Malaise	1
Muscle stiffness	1
Oedema	1
Site reaction	1
Tremor	1
Urticaria	1

The most reported side effects of vaccinations include vomiting, coughing, lethargy and diarrhoea. These occur very occasionally with most vaccines.

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CANINE PARAINFLUENZA

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Coughing	2
Frothing at the mouth	1
Sneezing	1

CANINE PARAINFLUENZA TYPE 2

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
11	0	11

PRESENTING SIGN	INCIDENCE
Lethargy	4
Allergy	3
Diarrhoea	3
Facial oedema	3
Pyrexia	3
Vomiting	3
Anorexia	2
Restless	2
Ataxia	1
Pain	1
Paresis	1
Pupillary light reflex (abnormal)	1
Weakness	1

The most reported side effects of vaccinations include vomiting, coughing, lethargy and diarrhoea. These occur very occasionally with most vaccines.

Due to the low number of reports when taking into consideration the large number of dogs vaccinated each year, no further regulatory action is required other than continuing monitoring for future adverse experience reports.

CANINE PARAINFLUENZA VIRUS

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
109	55	54

PRESENTING SIGN	INCIDENCE
Lethargy	44
Pain	32
Vomiting	28
Anorexia	21
Facial oedema	18
Shaking	14
Coughing	11
Injection site reaction	9
Urticaria	9
Depression	5
Pyrexia	5
Erythema	4
Pale mucous membranes	4
Pruritis	4
Collapse	3
Swollen lips and face	3
Tremor	3
Anaphylaxis	2
Disorientation	2
Malaise	2
Periorbital swelling	2
Vocalisation	2

PRESENTING SIGN	INCIDENCE
Weakness	2
Wheals	2
Agitation	1
Alopecia (localised)	1
Anaphylactoid reaction	1
Ataxia	1
Bradycardia	1
Diarrhoea	1
Distress	1
Dyspnoea	1
Haemorrhagic gastroenteritis	1
Hives	1
Hypersalivation	1
Hypotension	1
Lump (local)	1
Nasal discharge	1
Respiratory problems	1
Site reaction	1
Sneezing	1
Tachypnoea	1
Thrombocytopenia	1
Unconscious	1
Urination	1

The most reported side effects of vaccinations include vomiting, coughing, lethargy and diarrhoea. These occur very occasionally with most vaccines.

Due to the low number of reports when taking into consideration the large number of dogs vaccinated each year, no further regulatory action is required other than continuing monitoring for future adverse experience reports.

CANINE PARAINFLUENZA VIRUS - INACTIVATED

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
22	7	15

PRESENTING SIGN	INCIDENCE
Injection site reaction	14
Lump (local)	8
Pain	4
Pyrexia	3
Abscess	2
Lethargy	2
Anorexia	1
Collapse	1
Depression	1
Epistaxis	1
Facial oedema	1
Immune-mediated haemolytic anaemia	1
Leucopenia	1
Muscle stiffness	1
Oedema	1
Polyarthritis	1
Site reaction	1
Thrombocytopenia	1
Vomiting	1

CANINE PARVO VIRUS

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
20	2	18

PRESENTING SIGN	INCIDENCE
Lethargy	6
Vomiting	6
Facial oedema	4
Pyrexia	4
Allergy	3
Anorexia	3
Diarrhoea	3
Injection site reaction	2
Restless	2
Anaphylaxis	1
Ataxia	1
Coughing	1
Depression	1
Frothing at the mouth	1
Haemorrhagic gastroenteritis	1
Lack of effect	1
Lump (local)	1
Pain	1
Paresis	1
Pupillary light reflex (abnormal)	1
Weakness	1

CANINE PARVO VIRUS TYPE 2

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
82	53	29

PRESENTING SIGN	INCIDENCE
Lethargy	40
Pain	30
Vomiting	21
Facial oedema	17
Anorexia	16
Shaking	14
Urticaria	8
Injection site reaction	7
Erythema	4
Pale mucous membranes	4
Pruritis	4
Collapse	3
Depression	3
Pyrexia	3
Swollen lips and face	3
Disorientation	2
Tremor	2
Weakness	2
Wheals	2
Anaphylactoid reaction	1
Anaphylaxis	1
Ataxia	1

PRESENTING SIGN	INCIDENCE
Bradycardia	1
Coughing	1
Diarrhoea	1
Distress	1
Dyspnoea	1
Hives	1
Hypersalivation	1
Hypotension	1
Malaise	1
Site reaction	1
Site reaction (swelling)	1
Tachypnoea	1
Thrombocytopenia	1
Unconscious	1
Urination	1

CANINE PARVOVIRUS - LIVE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
16	5	11

PRESENTING SIGN	INCIDENCE
Injection site reaction	8
Lump (local)	6
Lethargy	3
Pain	3

Anorexia	2
Collapse	1
Epistaxis	1
Facial oedema	1
Immune-mediated haemolytic anaemia	1
Polyarthritis	1
Pyrexia	1
Thrombocytopenia	1

CANINE PARVO VIRUS STRAIN 154 - LIVE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
14	2	12

PRESENTING SIGN	INCIDENCE
Injection site reaction	5
Vomiting	5
Pain	3
Pyrexia	3
Abscess	2
Anorexia	2
Depression	2
Lump (local)	2
Periorbital swelling	2
Vocalisation	2
Agitation	1
Alopecia (localised)	1

PRESENTING SIGN	INCIDENCE
Lethargy	1
Leucopenia	1
Malaise	1
Muscle stiffness	1
Oedema	1
Site reaction	1
Tremor	1
Urticaria	1

The most reported side effects of vaccinations include vomiting, coughing, lethargy and diarrhoea. These occur very occasionally with most vaccines. Due to the low number of reports when taking into consideration the large number of dogs vaccinated each year, no further regulatory action is required other than continuing monitoring for future adverse experience reports.

CARBARYL

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Irritation (eye)	1
Red eyes	1
Swelling (local)	1

CARPROFEN

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Azotaemia	1
Coagulopathy	1
Haematemesis	1
Hepatopathy	1
Lethargy	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Renal failure	1

CEFTIOFUR AS CEFTIOFUR HYDROCHLORIDE

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Residue violation	1

CEFUROXIME SODIUM

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

CELLULASE

Porcine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	NUMBER OF REPORTS
Residue violation	1

CEPHALEXIN AS CEPHALEXIN MONOHYDRATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

PRESENTING SIGN	INCIDENCE
Lethargy	1
Vomiting	1

CHLAMYDOPHILIA FELIS BAKER STRAIN - LIVE, ATTENUATED

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	2	4

PRESENTING SIGN	INCIDENCE
Anorexia	3
Pain	3
Lethargy	2
Pyrexia	2
Behavioural change	1
Facial oedema	1
Malaise	1
Ocular discharge	1
Self trauma	1
Site reaction (swelling)	1
Sneezing	1
URTI	1

CHLORAMPHENICOL

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Allergy	1

CHLORFENVINPHOS

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Lack of effect	1

CHLORHEXIDINE GLUCONATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	2	1

PRESENTING SIGN	INCIDENCE
Hives	1
Hypersensitivity reaction	1
Pruritis	1

CHLORPHENIRAMINE MALEATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Bradycardia	1
Collapse	1
Seizure	1

CHLORPYRIFOS

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Lack of effect	2

CLAVULANIC ACID AS POTASSIUM CLAVULANATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Injection site reaction	2
Abscess	1
Lump (local)	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Injection site reaction	1

CLOMIPRAMINE HYDROCHLORIDE

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

PRESENTING SIGN	INCIDENCE
Anorexia	1
Constipation	1
Urinary retention	1

CLOSTRIDIUM BOTULINUM TYPE C TOXOID

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Death	1
Lack of effect	1
Paralysis	1

CLOSTRIDIUM BOTULINUM TYPE D TOXOID

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1		1

PRESENTING SIGN	INCIDENCE
Death	1
Lack of effect	1
Paralysis	1

CLOSTRIDIUM CHAUVOEI - FORMOL CULTURE

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Death	1

CLOSTRIDIUM CHAUVOEI - KILLED

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	0	6

PRESENTING SIGN	INCIDENCE
Injection site reaction	5
Abscess	1
Lump (local)	1
Swelling (local)	1

CLOSTRIDIUM CHAUVOEI - KILLED

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Abscess	1
Injection site reaction	1
Lump (local)	1

CLOSTRIDIUM CHAUVOEI - KILLED

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Injection site reaction	1
Lethargy	1
Lump (local)	1

CLOSTRIDIUM CHAUVOEI - TOXOID

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	0	6

PRESENTING SIGN	INCIDENCE
Injection site reaction	5
Abscess	1
Lump (local)	1
Swelling (local)	1

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Abscess	1
Injection site reaction	1
Lump (local)	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Injection site reaction	1
Lethargy	1
Lump (local)	1

CLOSTRIDIUM NOVYI TYPE B – KILLED

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	0	6

PRESENTING SIGN	INCIDENCE
Injection site reaction	5
Abscess	1
Lump (local)	1
Swelling (local)	1

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Abscess	1
Injection site reaction	1
Lump (local)	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Injection site reaction	1
Lethargy	1
Lump (local)	1

CLOSTRIDIUM NOVYI TYPE B - TOXOID

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
7	0	7

PRESENTING SIGN	INCIDENCE
Injection site reaction	5
Abscess	1
Death	1
Lump (local)	1
Swelling (local)	1

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Abscess	1
Injection site reaction	1
Lump (local)	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Injection site reaction	1
Lethargy	1
Lump (local)	1

CLOSTRIDIUM PERFRINGENS TYPE D TOXOID

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
7	0	7

PRESENTING SIGN	INCIDENCE
Injection site reaction	5
Abscess	1
Death	1
Lump (local)	1
Swelling (local)	1

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Abscess	1
Injection site reaction	1
Lump (local)	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Injection site reaction	1
Lethargy	1
Lump (local)	1

CLOSTRIDIUM SEPTICUM - TOXOID

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
7	0	7

PRESENTING SIGN	INCIDENCE
Injection site reaction	5
Abscess	1
Death	1
Lump (local)	1
Swelling (local)	1

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Abscess	1
Injection site reaction	1
Lump (local)	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Injection site reaction	1
Lethargy	1
Lump (local)	1

CLOSTRIDIUM TETANI - ANTITOXIN

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Death	2
Colic	1
Oedema	1
Stiffness	1

PRESENTING SIGN	INCIDENCE
Urticaria	1

CLOSTRIDIUM TETANI - TOXOID

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
7	0	7

PRESENTING SIGN	INCIDENCE
Injection site reaction	5
Abscess	1
Death	1
Lump (local)	1
Swelling (local)	1

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Abscess	1
Injection site reaction	1
Lump (local)	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Injection site reaction	1
Lethargy	1
Lump (local)	1

CLOSTRIDIUM TETANI UF TOXOID

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Death	1
Stiffness	1

CLOTRIMISOLE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

PRESENTING SIGN	INCIDENCE
Deafness	3

COBALT EDTA

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Death	1

COPPER SULFATE

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Diarrhoea	1

CORONA VIRUS

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

CYCLOSPORIN

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
25	18	7

PRESENTING SIGN	INCIDENCE
Vomiting	14
Diarrhoea	7
Lethargy	4
Agitation	2
Gingival hyperplasia	2
Hyperactivity	2
Tachypnoea	2
Abdominal pain	1
Alopecia	1
Anorexia	1
Ataxia	1
Behavioural change	1
Dehydration	1
Erythema	1
Irritation (skin)	1
Lack of effect	1
Muscle twitching	1
Pruritis	1
Restless	1
Tachycardia	1

CYPERMETHRIN

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Lack of effect	1

DELTAMETHRIN

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	2	2

PRESENTING SIGN	INCIDENCE
Behavioural change	2
Irritation (skin)	1
Lack of effect	1
Milk production decrease	1
Site reaction	1

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Behavioural change	1
Colic	1
Sweating	1

DEOXYCORTONE PIVALATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Pain	1

DERACOXIB

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Haematemesis	1
Vomiting	1

DESLORELIN AS DESLORELIN ACETATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
17	7	10

PRESENTING SIGN	INCIDENCE
Lack of effect	6
Allergy	2
Behavioural change	2
Low efficacy	2
Site reaction	2
Abscess	1

PRESENTING SIGN	INCIDENCE
Alopecia	1
Incontinence	1
Reproduction disorder	1

DEXTROMETHORPHAN HYDROBROMIDE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Bradycardia	1
Collapse	1
Seizure	1

DIAZINON

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	0	4

PRESENTING SIGN	INCIDENCE
Lack of effect	4

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Lack of effect	2

DICYCLANIL

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
9	0	9

PRESENTING SIGN	INCIDENCE
Lack of effect	9
Flystrike	2

DIFLUBENZURON

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
102	39	63

PRESENTING SIGN	INCIDENCE
Lack of effect	102

Diflubenzuron is an insect growth-regulating compound (IGR). An IGR is a material that controls the life cycle of pests such as cockroaches and fleas by inhibiting maturation of the pests. The sheep and wool industry rely heavily on the use of the insect growth regulator group of chemicals (IGRs) for treating lice. Unfortunately there are lice with reduced susceptibility to IGRs.

DIHYDROSEPTROMYCIN AS THE SULFATE

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Residue violation	1

DOXYCYCLINE AS DOXYCYCLINE MONOHYDRATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Hepatopathy	2

EIMERIA ACERVULINA OOCYSTS

Avian

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Lack of effect	1

EIMERIA MAXIMA OOCYSTS

Avian

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Lack of effect	1

EIMERIA NECATRIX OOCYSTS

Avian

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Lack of effect	1

EIMERIA TENELLA OOCYSTS

Avian

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Lack of effect	1

EMODEPSIDE

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
29	28	1

PRESENTING SIGN	INCIDENCE
Alopecia (localised)	25
Ataxia	1
Behavioural change	2
Burn(s)	1
Erythema	1

PRESENTING SIGN	INCIDENCE
Inflammation	1
Irritation (skin)	1
Lesions	1
Rash	1

ENROFLOXACIN

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	3	1

PRESENTING SIGN	INCIDENCE
Erythema	2
Hypersalivation	1
Inflammation	1
Injection site reaction	1
Swelling (local)	1
Ulceration	1
Vomiting	1

EPHEDRINE HYDROCHLORIDE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Bradycardia	1
Collapse	1
Seizure	1

EPRINOMECTIN

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	0	4

PRESENTING SIGN	INCIDENCE
Lack of effect	4

FEBANTEL

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
7	4	3

PRESENTING SIGN	INCIDENCE
Vomiting	3
Hyperactivity	2
Diarrhoea	1
Facial oedema	1
Hyperexcitable	1
Lethargy	1
Mydriasis	1
Restless	1
Shaking	1
Urticaria	1

FELINE CALICIVIRUS - INACTIVATED

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
24	12	12

PRESENTING SIGN	INCIDENCE
Lethargy	11
Anorexia	10
Pain	8
Pyrexia	6
Diarrhoea	5
Vomiting	5
Injection site reaction	4
Death	2
Erythema	2
Facial oedema	2
Pruritis	2
Alopecia (localised)	1
Anaphylaxis	1
Behavioural change	1
Depression	1
Gastroenteritis	1
Haematemesis	1
Hypotension	1
Malaise	1
Muscle stiffness	1
Ocular discharge	1
Pulmonary oedema	1

PRESENTING SIGN	INCIDENCE
Recumbency	1
Respiratory problems	1
Self trauma	1
Site reaction (swelling)	1
Sneezing	1
URTI	1

The most reported side effects of vaccinations in cats include lethargy, anorexia and pyrexia. These occur very occasionally with most vaccines. Due to the low number of reports when taking into consideration the large number of cats vaccinated each year, no further regulatory action is required other than continuing monitoring for future adverse experience reports.

FELINE LEUKAEMIA VIRUS – INACTIVATED

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

PRESENTING SIGN	INCIDENCE
Pain	2
Anorexia	1
Lethargy	1

FELINE PANLEUCOPENIA VIRUS - INACTIVATED

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
24	12	12

PRESENTING SIGN	INCIDENCE
Lethargy	11

PRESENTING SIGN	INCIDENCE
Anorexia	10
Pain	8
Pyrexia	6
Diarrhoea	5
Vomiting	5
Injection site reaction	4
Death	2
Erythema	2
Facial oedema	2
Pruritis	2
Alopecia (localised)	1
Anaphylaxis	1
Behavioural change	1
Depression	1
Gastroenteritis	1
Haematemesis	1
Hypotension	1
Malaise	1
Muscle stiffness	1
Ocular discharge	1
Pulmonary oedema	1
Recumbency	1
Respiratory problems	1
Self trauma	1
Site reaction (swelling)	1
Sneezing	1
URTI	1

The most reported side effects of vaccinations in cats include lethargy, anorexia and pyrexia. These occur very occasionally with most vaccines. Due to the low number of reports when taking into consideration the large number of cats vaccinated each year, no further regulatory action is required other than continuing monitoring for future adverse experience reports.

FELINE RHINOTRACHEITIS VIRUS - INACTIVATED

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
24	12	12

PRESENTING SIGN	INCIDENCE
Lethargy	11
Anorexia	10
Pain	8
Pyrexia	6
Diarrhoea	5
Vomiting	5
Injection site reaction	4
Death	2
Erythema	2
Facial oedema	2
Pruritis	2
Alopecia (localised)	1
Anaphylaxis	1
Behavioural change	1
Depression	1
Gastroenteritis	1
Haematemesis	1
Hypotension	1

PRESENTING SIGN	INCIDENCE
Malaise	1
Muscle stiffness	1
Ocular discharge	1
Pulmonary oedema	1
Recumbency	1
Respiratory problems	1
Self trauma	1
Site reaction (swelling)	1
Sneezing	1
URTI	1

The most reported side effects of vaccinations in cats include lethargy, anorexia and pyrexia. These occur very occasionally with most vaccines. Due to the low number of reports when taking into consideration the large number of cats vaccinated each year, no further regulatory action is required other than continuing monitoring for future adverse experience reports.

FENTHION

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Site reaction	1

FIPRONIL

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

Fipronil is a broad-spectrum phenyl pyrazole insecticide acting on the nervous system of insects by contact or ingestion. These are relatively new products in the market place and have a very high volume of sales. Fipronil is currently under review. Progress of the review can be monitored on the APVMA website (http://www.apvma.gov.au/chemrev/ChemRevProgram.shtml).

FIROCOXIB

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
10	2	8

PRESENTING SIGN	INCIDENCE
Lethargy	4
Vomiting	4
Anorexia	2
Blood in faeces	2
Collapse	2
Death	2
Diarrhoea	2
Melaena	2
Abdominal pain	1
Azotaemia	1
Thrombocytopenia	1
Ulceration (stomach)	1

FLUAZURON

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Lack of effect	1

FLUMETHRIN

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Irritation (skin)	1
Rolling	1

FORMALIN

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

PRESENTING SIGN	INCIDENCE
Injection site reaction	2
Anorexia	1
Oedema	1

FUNGAL PROTEASE

Porcine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Residue violation	1

GENTAMYCIN

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

PRESENTING SIGN	INCIDENCE
Deafness	3

HEPATITIS CANINE = CANINE ADENOVIRUS

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

HYOSCINE AS HYOSCINE METHOBROMIDE

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Residue violation	1

IMIDACLOPRID

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
274	237	37

PRESENTING SIGN	INCIDENCE
Irritation (skin)	98
Behavioural change	62
Restless	44
Lethargy	39
Paraesthesia	33
Agitation	32
Site reaction	30
Vomiting	26
Anorexia	17
Lack of effect	17
Shaking	17
Inflammation	15
Depression	14
Dermatitis	14
Erythema	14

PRESENTING SIGN	INCIDENCE
Alopecia (localised)	12
Rolling	12
Rubbing	12
Self trauma	12
Hyperexcitable	11
Distress	10
Scabs	9
Diarrhoea	8
Panting	8
Ataxia	6
Rash	5
Pruritis	4
Lesions	3
Red eyes	3
Urticaria	3
Adipsia	2
Burn(s)	2
CNS dysfunction	2
Polydipsia	2
Pustules	2
Respiratory problems	2
Tick paralysis	2
Walking (difficult)	2
Welts	2
Abscess	1
Blisters	1
Blood in faeces	1

PRESENTING SIGN	INCIDENCE
Burning sensation	1
Conjunctivitis	1
Crusting skin	1
Epiphora	1
Excitation	1
Facial oedema	1
Hallucinating	1
Hyperactivity	1
Hyperaesthesia	1
Hypothermia	1
Incontinence	1
Irritation (ear)	1
Irritation (eye)	1
Lump (local)	1
Muscle twitching	1
Nausea	1
Nil	1
Otitis externa	1
Paresis	1
Site reaction (swelling)	1
Skin slough	1
Spasm	1
Toxicity	1
Tremor	1
Unknown	1
Vocalisation	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
53	46	7

PRESENTING SIGN	INCIDENCE
Alopecia (localised)	23
Dermatitis	6
Lesions	5
Alopecia	4
Vomiting	4
Behavioural change	3
Hypersalivation	3
Rash	3
Scabs	3
Anorexia	2
Ataxia	2
Frothing at the mouth	2
Inflammation	2
Lethargy	2
Self trauma	2
Site reaction	2
Agitation	1
Blindness	1
CNS dysfunction	1
Depression	1
Distress	1
Erythema	1
Hyperaesthesia	1

PRESENTING SIGN	INCIDENCE
Irritation (skin)	1
Nil	1
Polydipsia	1
Tachypnoea	1
Tremor	1
Ulceration	1

INACTIVATED SALMONELLA DUBLIN & TYPHIMURIUM ANTIGENS

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Scouring	1

INFECTIOUS LARYNGOTRACHEITIS VIRUS STRAIN S.A.2

Avian

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Death	1

INSULIN

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Oedema	1
Site reaction	1
Swelling (local)	1

IVERMECTIN

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	1	3

PRESENTING SIGN	INCIDENCE
Site reaction	2
Alopecia (localised)	1
Dermatitis	1
Lack of effect	1
Lesions	1

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

PRESENTING SIGN	INCIDENCE
Diarrhoea	2
Vomiting	2

PRESENTING SIGN	INCIDENCE
Abdominal pain	1
Depression	1

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	4	0

PRESENTING SIGN	INCIDENCE
Hypersalivation	2
Swelling (local)	2
Anorexia	1
Lethargy	1
Oedema	1
Site reaction (swelling)	1
Swollen lips and face	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	1	3

PRESENTING SIGN	INCIDENCE
Lack of effect	4

LEPTOSPIRA BORGPETERSENII SEROVAR HARDJO

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Death	1

LEPTOSPIRA INTERROGANS SEROVAR POMONA

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Death	1

LEPTOSPIROSIS - DOG - LEPTOSPIRA ICTEROHAEMORRHAGIAE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

LEVAMISOLE HYDROCHLORIDE

Avian

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Death	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Death	1
Pale mucous membranes	1

LINCOMYCIN AS LINCOMYCIN HYDROCHLORIDE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Cyanosis	1
Vomiting	1

LUFENURON

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
11	4	7

PRESENTING SIGN	INCIDENCE
Diarrhoea	4
Vomiting	4
Anorexia	2
Ataxia	2
Distress	2
Lack of effect	2
Convulsions	1
Haematology (abnormal)	1
Hyperaesthesia	1
Hypersalivation	1
Incontinence	1
Lethargy	1
Miosis	1
Panting	1
Somnolence	1
Stiffness	1
Tachypnoea	1
Weakness	1

M.HYOPNEUMONIA – INACTIVATED WHOLE CELL CULTURE

Porcine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Death	2
Respiratory problems	2
Vomiting	2
Ataxia	1
Behavioural change	1

MELALEUCA OIL

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Irritation (skin)	1

MELOXICAM

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

PRESENTING SIGN	INCIDENCE
Anaphylactoid reaction	2

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

PRESENTING SIGN	INCIDENCE
Vomiting	3
Anorexia	2
Abdominal pain	1
Azotaemia	1
Dehydration	1
Diarrhoea	1
Haemorrhagic gastroenteritis	1
lllthrift	1
Melaena	1
Neutrophilia	1
Renal failure	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Coagulopathy	1
Hypotension	1
Renal failure	1

METHOPRENE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Lack of effect	2

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

PRESENTING SIGN	INCIDENCE
Ataxia	1
Hypersalivation	1
Incoordination	1
Lethargy	1

MICONAZOLE NITRATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	2	1

PRESENTING SIGN	INCIDENCE
Hives	1
Hypersensitivity reaction	1
Pruritis	1

MILBEMYCIN OXIME

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
16	6	10

PRESENTING SIGN	INCIDENCE
Vomiting	5
Diarrhoea	4
Ataxia	3
Lethargy	3
Anorexia	2
Distress	2
Lack of effect	2
Convulsions	1
Epistaxis	1
Facial oedema	1
Haematology (abnormal)	1
Hyperaesthesia	1
Hypersalivation	1
Incontinence	1
Miosis	1
Panting	1
Pruritis	1
Somnolence	1
Stiffness	1
Tachypnoea	1
Walking (difficult)	1
Weakness	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

PRESENTING SIGN	INCIDENCE
Ataxia	1
Lethargy	1
Vomiting	1

MORAXELLA BOVIS

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
22	2	20

PRESENTING SIGN	INCIDENCE
Lack of effect	19
Anaphylaxis	1
Bloat	1
Death	1
Dyspnoea	1
Hypersalivation	1
Injection site reaction	1
Lump (local)	1
Tachycardia	1

MOXIDECTIN

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	3	3

PRESENTING SIGN	INCIDENCE
Ataxia	4
Recumbency	3
Death	2
Hypersalivation	2
Blood in faeces	1
Convulsions	1
Depression	1
Frothing at the mouth	1
Frothing at the nose	1
Haemorrhage	1
Lack of effect	1
Mydriasis	1
Respiratory problems	1
Swelling (local)	1

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
50	21	29

PRESENTING SIGN	INCIDENCE
Vomiting	19
Lethargy	12

PRESENTING SIGN	INCIDENCE
Facial oedema	6
Diarrhoea	5
Urticaria	5
Alopecia (localised)	4
Behavioural change	3
Irritation (skin)	3
Pruritis	3
Shaking	3
Site reaction	3
Agitation	2
Anorexia	2
Burn(s)	2
Depression	2
Anaphylactoid reaction	1
Anaphylaxis	1
Conjunctivitis	1
Dermatitis	1
Erythema	1
Haemorrhagic gastroenteritis	1
Incontinence	1
Injection site reaction	1
Lack of effect	1
Lesions	1
Nil	1
Otitis externa	1
Pustules	1
Pyrexia	1

PRESENTING SIGN	INCIDENCE
Red eyes	1
Respiratory problems	1
Swollen lips and face	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
34	29	5

PRESENTING SIGN	INCIDENCE
Alopecia (localised)	12
Alopecia	4
Rash	3
Scabs	3
Vomiting	3
Anorexia	2
Ataxia	2
Frothing at the mouth	2
Hypersalivation	2
Inflammation	2
Lethargy	2
Behavioural change	1
Blindness	1
CNS dysfunction	1
Depression	1
Distress	1
Hyperaesthesia	1
Irritation (skin)	1
Lesions	1

Nil	1
Polydipsia	1
Self trauma	1
Tremor	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Lack of effect	1
Lethargy	1
Stiffness	1
Walking (difficult)	1

Moxidectin is often used in conjunction with other products, resulting in a higher incidence of reporting. These products have a very high volume of sales and several new products have been released. A few products have a reporting incidence approaching warning levels and these products are being closely monitored.

Note : Moxidectin and Moxidectin Microspheres are reported under the active Moxidectin in this report.

MYCOPLASMA HYOPNEUMONIAE – INACTIVATED ANTIGEN

Porcine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Anaphylactoid reaction	1
Death	1
Vomiting	1

MYO-INOSITOL-HEXAPHOSPHATE PHOSPHOHYDROLASE

Porcine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Residue violation	1

NIGERGOLINE FREEZE DRIED

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lethargy	1
Vomiting	1

NICLOSAMIDE

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

PRESENTING SIGN	INCIDENCE
Behavioural change	1
Diarrhoea	1
Vomiting	2

NICLOSAMIDE MONOHYDRATE - MICRONISED

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Illness	1

NITENPYRAM

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Hypersensitivity reaction	1
Lethargy	1
Oedema	1
Urticaria	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	4	1

PRESENTING SIGN	INCIDENCE
Irritation (skin)	4
Panting	3
Agitation	2
Distress	2
Pyrexia	1

PRESENTING SIGN	INCIDENCE
Tachycardia	1
Tachypnoea	1

N-OCTYL BICYCLOHEPTENE DICARBOXIMIDE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
8	1	7

PRESENTING SIGN	INCIDENCE
Erythema	1
Lack of effect	6
Restless	1
Site reaction	1
Tick paralysis	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	1	3

PRESENTING SIGN	INCIDENCE
Ataxia	1
Hypersalivation	1
Illness	1
Incoordination	1
Lethargy	1

OATMEAL EXTRACT

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	2	0

PRESENTING SIGN	INCIDENCE
Irritation (eye)	1

OESTRADIOL 17-BETA

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

PRESENTING SIGN	INCIDENCE
Prolapse	2

OXANTEL EMBONATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

OXFENDAZOLE

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Death	1

OXYTETRACYCLINE HYDROCHLORIDE

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

PRESENTING SIGN	INCIDENCE
Ataxia	1
Collapse	1
Death	1
Oedema	1
Swollen ears and face	1

PARVOVIRUS - LIVE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

PECTINASE

Porcine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Residue violation	1

PENTOBARBITONE SODIUM

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Lack of effect	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Lack of effect	1

PERMETHRIN

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
26	25	1

PRESENTING SIGN	INCIDENCE
Paraesthesia	21
Dermatitis	6
Behavioural change	5
Alopecia (localised)	2
Lethargy	2
Site reaction	2
Ataxia	1
Depression	1
Epiphora	1
Panting	1
Restless	1
Vomiting	1

Permethrin is a common synthetic chemical, widely used as an insecticide, acaricide, and insect repellent. Permethrin is often used in conjunction with other products, resulting in a higher incidence of reporting. These products have a very high volume of sales.

PERMETHRIN (25:75: :CIS:TRANS)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Lack of effect	2

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Hypersensitivity reaction	1
Welts	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Seizure	1

PERMETHRIN (40:60: :CIS:TRANS)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
206	187	19

PRESENTING SIGN	INCIDENCE
Irritation (skin)	96

PRESENTING SIGN	INCIDENCE
Behavioural change	48
Restless	43
Agitation	30
Lethargy	30
Site reaction	26
Lack of effect	16
Inflammation	15
Anorexia	14
Erythema	14
Shaking	14
Vomiting	14
Depression	12
Paraesthesia	12
Rolling	12
Rubbing	12
Self trauma	12
Hyperexcitable	11
Distress	10
Scabs	9
Dermatitis	7
Panting	6
Rash	6
Ataxia	4
Alopecia (localised)	3
Blisters	3
Diarrhoea	3
Adipsia	2

PRESENTING SIGN	INCIDENCE
CNS dysfunction	2
Lesions	2
Polydipsia	2
Pruritis	2
Red eyes	2
Respiratory problems	2
Tick paralysis	2
Walking (difficult)	2
Welts	2
Abscess	1
Allergy	1
Blood in faeces	1
Burning sensation	1
Convulsions	1
Crusting skin	1
Excitation	1
Frothing at the mouth	1
Hallucinating	1
Hyperactivity	1
Hyperaesthesia	1
Hypothermia	1
Irritation (ear)	1
Irritation (eye)	1
Lump (local)	1
Muscle twitching	1
Nausea	1
Paresis	1

PRESENTING SIGN	INCIDENCE
Pustules	1
Site reaction (swelling)	1
Skin slough	1
Spasm	1
Toxicity	1
Unknown	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Poisoning	1

PIMOBENDAN

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Diarrhoea	1
Melaena	1

PIPERONYL BUTOXIDE

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	0	5

PRESENTING SIGN	INCIDENCE
Lack of effect	5

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
10	1	9

PRESENTING SIGN	INCIDENCE
Lack of effect	7
Corneal ulcer	1
Erythema	1
Irritation (eye)	1
Restless	1
Site reaction	1
Tick paralysis	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	1	4

PRESENTING SIGN	INCIDENCE
Ataxia	1
Hypersalivation	1
Illness	1
Incoordination	1

PRESENTING SIGN	INCIDENCE
Lethargy	1
Seizure	1

POLYMYXIN B SULFATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Allergy	1

PRAZIQUANTEL

Avian

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1		1

PRESENTING SIGN	INCIDENCE
Death	1

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
23	10	13

PRESENTING SIGN	INCIDENCE
Vomiting	8
Diarrhoea	5
Lethargy	4
Ataxia	3

PRESENTING SIGN	INCIDENCE
Lack of effect	3
Anorexia	2
Distress	2
Facial oedema	2
Hyperactivity	2
Convulsions	1
Haematology (abnormal)	1
Hyperaesthesia	1
Hyperexcitable	1
Hypersalivation	1
Incontinence	1
Miosis	1
Mydriasis	1
Panting	1
Pruritis	1
Restless	1
Shaking	1
Somnolence	1
Stiffness	1
Tachypnoea	1
Urticaria	1
Walking (difficult)	1
Weakness	1

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	4	0

PRESENTING SIGN	INCIDENCE
Hypersalivation	2
Swelling (local)	2
Anorexia	1
Lethargy	1
Oedema	1
Site reaction (swelling)	1
Swollen lips and face	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
34	32	2

PRESENTING SIGN	INCIDENCE
Alopecia (localised)	25
Ataxia	4
Behavioural change	2
Lethargy	2
Burn(s)	1
Disorientation	1
Erythema	1
Incoordination	1

PRESENTING SIGN	INCIDENCE
Inflammation	1
Irritation (skin)	1
Lesions	1
Rash	1
Vomiting	1

Praziquantel is a systemic anthelmintic used primarily to treat worm infections. Due to the low number of reports when taking into consideration the large number of animals treated each year, no further regulatory action is required other than continuing monitoring for future adverse experience reports.

PROCAINE PENICILLIN

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	3	1

PRESENTING SIGN	INCIDENCE
Death	3
Ataxia	2
Anaphylaxis	1
Restless	1
Shaking	1
Stiffness	1

PROPOFOL

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
36	28	8

PRESENTING SIGN	INCIDENCE
Facial oedema	17
Erythema	9
Hives	9
Welts	8
Bradycardia	5
Cardiac arrest	3
Urticaria	3
Wheals	3
Hypersensitivity reaction	2
Anaphylaxis	1
Apnoea	1
Cyanosis	1
Death	1
Dyspnoea	1
Hypotension	1
Paddling	1
Pain	1
Pulmonary oedema	1
Rash	1
Site reaction (swelling)	1
Swelling (local)	1

PYRANTEL AS PYRANTEL EMBONATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
11	4	7

PRESENTING SIGN	INCIDENCE
Vomiting	5
Diarrhoea	3
Hyperactivity	2
Abdominal pain	1
Depression	1
Facial oedema	1
Hyperexcitable	1
Lack of Effect	1
Lethargy	1
Mydriasis	1
Restless	1
Shaking	1
Urticaria	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	4	2

PRESENTING SIGN	INCIDENCE
Ataxia	2
Behavioural change	1
Diarrhoea	1
Disorientation	1

PRESENTING SIGN	INCIDENCE
Illness	1
Incoordination	1
Lethargy	1
Vomiting	1

PYRETHRINS

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
10	1	9

PRESENTING SIGN	INCIDENCE
Lack of effect	7
Corneal ulcer	1
Erythema	1
Irritation (eye)	1
Restless	1
Site reaction	1
Tick paralysis	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	1	3

PRESENTING SIGN	INCIDENCE
Ataxia	1
Hypersalivation	1

PRESENTING SIGN	INCIDENCE
Illness	1
Incoordination	1
Lethargy	1

PYRIPROXYFEN

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

PRESENTING SIGN	INCIDENCE
Allergy	1
Blisters	1
Erythema	1
Rash	1
Site reaction	1

(S)-METHOPRENE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Illness	1

(S)-methoprene is often used in conjunction with other products resulting in a higher incidence of reporting. (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.

SELAMECTIN

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
9	6	3

PRESENTING SIGN	INCIDENCE
Alopecia (localised)	4
Site reaction	4
Pruritis	2
Erythema	1

PRESENTING SIGN	INCIDENCE
Facial oedema	1
Irritation (skin)	1
Shaking	1
Tremor	1
Urticaria	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
32	31	1

PRESENTING SIGN	INCIDENCE
Alopecia (localised)	29
Site reaction	9
Dermatitis	2
Behavioural change	1
Lethargy	1
Pruritis	1

SELENIUM AS SODIUM SELENATE

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Injection site reaction	1
Swelling (local)	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	3	1

PRESENTING SIGN	INCIDENCE
Injection site reaction	1
Death	1
Lack of effect	1
Lethargy	2
Lump (local)	1
Stiffness	1
Walking (difficult)	1

SILVER SULFADIAZINE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

PRESENTING SIGN	INCIDENCE
Erythema	2
Inflammation	1
Swelling (local)	1
Ulceration	1

SODIUM PENTOSAN POLYSULFATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	1	3

PRESENTING SIGN	INCIDENCE
Agitation	1
Anorexia	1
Ataxia	1
Behavioural change	1
Diarrhoea	1
Lethargy	2
Pain	1
Pyrexia	1
Vomiting	1

SPECTINOMYCIN AS SPECTINOMYCIN SULFATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Cyanosis	1
Vomiting	1

SPINOSAD

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	1	4

PRESENTING SIGN	INCIDENCE
Lack of effect	5

SULFADIAZINE

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Residue violation	1

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

PRESENTING SIGN	INCIDENCE
Anaphylaxis	2
Collapse	1
Death	1

SULFADIMIDINE

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Residue violation	1

TRICLABENDAZOLE

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Dermatitis	1
Lack of effect	1

TRIFLUMURON

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
11	10	1

PRESENTING SIGN	INCIDENCE
Lack of effect	11

TRIMETHOPRIM

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

PRESENTING SIGN	INCIDENCE
Anaphylaxis	2
Collapse	1
Death	1

VITAMIN A

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Diarrhoea	1

VITAMIN B1 – THIAMINE HYDROCHLORIDE

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Residue violation	1

VITAMIN D3

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Diarrhoea	1

VITAMIN E

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Diarrhoea	1

XYLANASE

Porcine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Residue violation	1

ZETA-CYPERMETHRIN

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	0	5

PRESENTING SIGN	INCIDENCE
Lack of effect	5

ZINC EDTA

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Death	1

3 VETERINARY - SUMMARY OF ADVERSE EXPERIENCE REPORTS 2008 (HUMAN)

3.1 Adverse experience report summaries involving humans listed by active constituent

The following information is contained in this section:

Active constituent name

Each active constituent is listed alphabetically, with a summary of the adverse experience reports. It is important to note that the number of adverse experience reports and the presenting signs observed may be listed under more than one active constituent if they refer to a product that contains multiple active constituents.

Number of reports

Only adverse experience reports that were classified by the APVMA during the calendar year 2007, as being either probable or possible have been included in these lists. The summary table indicates how many reports were classified as probable and how many were classified as possible.

Presenting signs

All observed clinical signs for reports that were classified as probable and possible are listed in order of frequency.

It is important to note that multiple clinical signs may have been noted in some individual reports. Therefore the list of clinical signs observed does not relate directly to the total number of reports received.

3.2 Veterinary – Human AERs

CHLORFENVINPHOS

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Dizziness	1
Shaking	1

CLOSTRIDIUM CHAUVOEI - TOXOID

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Needle stick injury	1

CLOSTRIDIUM CHAUVOEI TOXIOD AND INACTIVATED CELLS

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Needle stick injury	1

CLOSTRIDIUM NOVYI TYBE B TOXIOD AND INACTIVATED CELLS

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1		1

Presenting sign	Incidence
Needle Stick	1

CLOSTRIDIUM PERFRINGES TYPE D TOXOID

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Needle stick injury	1

CLOSTRIDIUM SEPTICUM - TOXOID

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Needle stick injury	1

CLOSTRIDIUM TETANI - TOXOID

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Needle stick injury	1

COLLOIDAL OATMEAL

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Erythema	1
Pruritis	1

CORYNEBACTERIUM PSEUDOTUBERCULOSIS TOXOID AND INACTIVATE

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Needle stick injury	1

CYPERMETHRIN

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Dizziness	1
Shaking	1

FIPRONIL

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Inflammation	1
Irritation (eye)	1
Red eyes	1

IMIDACLOPRID

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	3	0

PRESENTING SIGN	INCIDENCE
Agitation	2
Behavioural change	1

PRESENTING SIGN	INCIDENCE
Burning sensation	1
Irritation (skin)	1
Muscle twitching	1
Restless	1

MOXIDECTIN

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

PRESENTING SIGN	INCIDENCE
Agitation	1
Behavioural change	1
Burning sensation	1

MYCOBACTERIUM PARATUBERCULOSIS

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Erythema	1

N-OCTYL BICYCLOHEPTENE DICARBOXIMIDE

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	1

PRESENTING SIGN	INCIDENCE
Allergy	1

PERMETHRIN (40:60: :CIS:TRANS)

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Agitation	1
Irritation (skin)	1
Muscle twitching	1
Restless	1

PIPERONYL BUTOXIDE

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Allergy	1

PYRETHRINS

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Allergy	1

(S)-METHOPRENE

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Inflammation	1
Irritation (eye)	1
Red eyes	1

SELAMECTIN

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Burning sensation	1

4 AGRICULTURE - SUMMARY OF ADVERSE EXPERIENCE REPORTS 2008 (STANDARD)

4.1 Adverse experience report summaries involving crop damage, domestic animal harm, environmental damage or lack of efficacy listed by active constituent

The following information is contained in this section:

Active constituent name

- Each active constituent is listed alphabetically, with a summary of the adverse experience reports.
- It is important to note that the number of adverse experience reports and the presenting signs observed may be listed under more than one active constituent if they refer to a product that contains multiple active constituents.

Number of reports

- Only adverse experience reports that were classified by the APVMA during the calendar year 2007, as being either probable or possible have been included in these lists. The summary table indicates how many reports were classified as probable and how many were classified as possible.

Presenting signs

- All observed effects for reports that were classified as probable and possible are listed in order of frequency.
- It is important to note that multiple adverse effects have been noted in some individual reports. Therefore the list of observed effects does not relate directly to the total number of reports received.

4.2 Agriculture Chemical - Standard AERs

BACILLUS THURINGIENSIS SUBSP KURSTAKI DELTA ENDOTOXINS A

Cotton

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Crop damage	1

BUPROFEZIN

Table Grapes

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

DIURON

Water / Pond

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1		1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

INDOXACARB (25:75)

Canola

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	

PRESENTING SIGN	INCIDENCE
Residue violation	1

MCPA PRESENT AS THE POTASSIUM SALT

Cotton

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	

PRESENTING SIGN	INCIDENCE
Crop damage	1

TERBUTRYN

Cotton

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	

PRESENTING SIGN	INCIDENCE
Crop damage	1

5 AGRICULTURE - SUMMARY OF ADVERSE EXPERIENCE REPORTS 2008 (HUMAN)

5.1 Adverse experience report summaries involving humans listed by active constituent

The following information is contained in this section:

Active constituent name

Each active constituent is listed alphabetically, with a summary of the adverse experience reports.

It is important to note that the number of adverse experience reports and the presenting signs observed may be listed under more than one active constituent if they refer to a product that contains multiple active constituents.

Number of reports

Only adverse experience reports that were classified by the APVMA during the calendar year 2007, as being either probable or possible have been included in these lists. The summary table indicates how many reports were classified as ‘probable’ and how many were classified as possible.

Presenting signs

All observed clinical signs for reports that were classified as probable and possible are listed in order of frequency.

It is important to note that multiple adverse effects have been noted in some individual reports. Therefore the list of observed effects does not relate directly to the total number of reports received.

5.2 Agriculture Chemical - Human AERs

BIFENTHRIN

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	NUMBER OF REPORTS
Burning sensation	1
Dyspnoea	1
Headache	1
Nasal discharge	1
Numbness	1
Ocular discharge	1

GLYPHOSATE PRESENT AS THE POTASSIUM SALT

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	

PRESENTING SIGN	INCIDENCE
Irritation (eye)	1
Red eyes	1

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GLOSSARY

Adipsia	Absence of thirst or abnormal avoidance of drinking
Alopecia	Absence of hair from areas where it is normally present
Analgesic	Pain relieving treatment
Anaphylactoid	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
Antimicrobial	An agent that kills micro-organisms or suppresses their multiplication or growth
Ataxia	Unsteady walking action due to muscular incoordination
Bradycardia	Excessive slowness in the action of the heart
Coagulopathy	Any disorder of blood coagulation
Colic	A general term for abdominal pain
Conjunctivitis	Conjunctivitis is the inflammation of the conjunctiva, a thin, delicate membrane that covers the eyeball and lines the eyelid
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
Epiphora	Diseases of the lacrimal apparatus
Epistaxis	Bleeding from the nose
Erythema	Abnormal redness of the skin due to local congestion, as in inflammation
Fasciculation	Involuntary contractions or twitchings of groups of muscle fibers
Folliculitis	Inflammation of the follicles
Haematemesis	Vomiting of blood
Haemorrhage	Bleeding
Hepatopathy	Disease or disorder of the liver
Hypersalivation	Excessive salivation
Hypersensitivity	An excessive reaction to an allergen

Intramammary	Within or into the mammary gland
Jaundice	Yellowish staining of the skin and mucous membranes
Melaena	The passage of dark stools 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 tendancy to vomit
Necrosis	Pathological process associated with severe cellular trauma
Oedematous	Abnormal accumulation of fluid in body cavities and under the skin
Paraesthesia	An abnormal sensation
Parasiticide	An agent that is destructive to parasites
Periorbital	Surrounding the eyes
Petechiae	Purplish or brownish red discoloration, caused by hemorrhage into the tissues
Preputial	Of or pertaining to the prepuce
Prolapse	To fall or slip out of place
Pruritis	Irritation and intense itching
Pyrexia	High fever
Rales	Abnormal respiratory sound heard on auscultation, indicating some pathologic condition
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
Tenesmus	Ineffectual and painful straining in an attempt to urinate or defecate
Thrombocytopenia	Decrease in the number of blood platelets
Urticaria	Vascular reaction of the skin as a result of contact with a chemical or may be immunologically based.
Wheals	A small swelling on the skin, as from an insect bite, that usually itches or burns
Withholding period	The time interval after the withdrawal of a drug or chemical use, to either the time of re-entry, harvesting or use of an animal or animal product for human consumption

LIST OF ACTIVE CONSTITUENTS