This serves as the response to your Freedom of Information Act (FOIA) request for records regarding adverse event reports received for afoxolaner and fluralaner.

A search of CVM's Adverse Drug Event (ADE) database was performed on 11/23/2015. The search parameters were:

| | |
|---|---|
| Active ingredient(s): | afoxolaner and fluralaner |
| Reports received: | From 1/1/2013 through 6/17/2015 |
| Case type: | Spontaneous ADE report |

For each drug, we have provided the '**CVM ADE Comprehensive Clinical Detail Report Listing**', which is a cumulative listing of adverse experiences in reports submitted to CVM.

General Information about CVM's ADE Database

The primary purpose for maintaining the CVM ADE database is to provide an early warning or signaling system to CVM for adverse effects not detected during pre-market testing of FDA-approved animal drugs and for monitoring the performance of drugs not approved for use in animals. Information from these ADE reports is received and coded in an electronic FDA/CVM ADE database. CVM scientists use the ADE database to make decisions about product safety which may include changes to the label or other regulatory action. CVM's ADE reporting system depends on detection and voluntary reporting of adverse clinical events by veterinarians and animal owners.

The Center's ADE review process is complex, and for each report takes into consideration confounding factors such as:

- Dosage
- Concomitant drug use
- The medical and physical condition of animals at the time of treatment
- Environmental and management information
- Product defects
- Extra-label (off label) uses

The specifics of these complex factors cannot be addressed in the CVM ADE Comprehensive Clinical Detail Report Listing.

## How to Use the CVM ADE Comprehensive Clinical Detail Report Listing

Clinical signs reported for an active ingredient are listed in order from most frequently reported to least frequently reported, grouped by species and route of administration.

**More than one clinical sign may have been reported per ADE case report, so the 'Number of times reported' column is not additive and does not necessarily represent the total number of reports received.** Also, if a manufacturer reports multiple products in a single ADE case report, clinical signs are associated with each of the manufacturer's products.

Afoxolaner and fluralaner are both approved for oral use in dogs only. For the time period of the ADE database search (1/1/2013 - 6/17/2015), there were a total of 5,087 ADE reports received for afoxolaner for dogs, and a total of 2,467 ADE reports received for fluralaner for dogs.

When reviewing the CVM ADE Comprehensive Clinical Detail Report Listing, the reader should be aware that:

- For any given ADE report, there is no certainty that the reported drug caused the adverse event. The adverse event may have been related to an underlying disease, using other drugs at the same time, or other non-drug related causes. The clinical detail listing does not include information about underlying diseases, other drugs used at the same time, other non-drug related causes, or the final outcome of the reaction.
- The accuracy of information regarding the ADE is dependent on the quality of information received from the reporting veterinarian or animal owner.
- Accumulated ADE reports should not be used to calculate incidence rates or estimates of drug risk, because there is no accurate way to determine how many animals were given the drug, which is needed as the denominator in calculations of incidence and relative risk.
- It is inappropriate to make use of adverse event data to compare the safety of different products. For example, if a drug is widely used to treat certain conditions, there may be more ADEs for that drug than another product that is not used as often. This would not mean that the first drug was more unsafe than the second. The number of reports simply represents the number of ADEs received for a particular drug and should not be used for any type of comparison purposes.
- Underreporting occurs with most adverse event reporting systems. The frequency of reporting for a given drug product varies over time, and may be greater when the drug is newly marketed, or when media publicity occurs.
- Information on how the drugs were used (for indications on the product label or in an extra label manner) is not provided in the clinical detail listing.

More information about CVM's ADE Reporting System can be found on our web site at: http://www.fda.gov/AnimalVeterinary/SafetyHealth/default.htm.

# CVM ADE Comprehensive Clinical Detail Report Listing

**Cumulative Date Range : 01-Jan-2013 -thru- 17-Jun-2015**
**For case type: Spontaneous**

## DRUG: FLURALANER

Species: Cat
Route of Administration: ORAL

| Sign : | Number of Times Reported : |
|---|---|
| ACCIDENTAL EXPOSURE | 1 |
| BEHAVIOURAL DISORDER NOS | 1 |
| DECREASED ACTIVITY | 1 |
| VOMITING | 1 |

Species: Dog
Route of Administration: MISSING

| Sign : | Number of Times Reported : |
|---|---|
| VOMITING | 1 |

Species: Dog
Route of Administration: ORAL

| Sign : | Number of Times Reported : |
|---|---|
| VOMITING | 1,025 |
| LETHARGY | 238 |
| DIARRHOEA | 225 |
| EMESIS (MULTIPLE) | 84 |
| ANOREXIA | 82 |
| PRURITUS | 80 |
| SEIZURE NOS | 56 |
| BEHAVIOURAL DISORDER NOS | 54 |
| ABNORMAL TEST RESULT | 51 |
| DECREASED APPETITE | 47 |
| INEFFECTIVE, FLEAS | 44 |

| | |
|---|---|
| INAPPETENCE | **42** |
| POLYDIPSIA | **41** |
| BLOODY DIARRHOEA | **32** |
| NOT EATING | **30** |
| FEVER | **29** |
| ELEVATED ALT | **28** |
| DEATH BY EUTHANASIA | **27** |
| POLYURIA | **27** |
| HIVES | **26** |
| WEIGHT LOSS | **26** |
| ALLERGIC REACTION | **25** |
| SCRATCHING | **24** |
| LOOSE STOOL | **22** |
| PANTING | **21** |
| ABNORMAL RADIOGRAPH FINDING | **20** |
| ATAXIA | **19** |
| DEATH | **19** |
| ELEVATED SAP | **19** |
| LEUCOCYTOSIS | **18** |
| SHAKING | **17** |
| TREMBLING | **17** |
| DEHYDRATION | **16** |
| FLATULENCE | **16** |
| INAPPROPRIATE URINATION | **16** |
| DEPRESSION | **15** |
| EMESIS | **15** |
| RESTLESSNESS | **15** |
| VOCALISATION | **15** |
| ABNORMAL ULTRASOUND FINDING | **14** |
| ITCHING | **14** |

| | |
|---|---|
| LACK OF EFFICACY | **14** |
| NOT DRINKING | **14** |
| ABDOMINAL PAIN | **13** |
| DROOLING | **13** |
| FACIAL SWELLING | **12** |
| HIDING | **12** |
| INAPPROPRIATE DEFECATION | **12** |
| URINARY TRACT INFECTION | **12** |
| ANAEMIA NOS | **11** |
| REDDENING OF THE SKIN | **11** |
| GENERAL PAIN | **10** |
| GENERALISED ITCHING | **10** |
| HYPERSALIVATION | **10** |
| INEFFECTIVE, TICKS | **10** |
| NEUTROPHILIA | **10** |
| PALE MUCOUS MEMBRANE | **10** |
| RETCHING | **10** |
| WALKING DIFFICULTY | **10** |
| ADIPSIA | **9** |
| CIRCLING | **9** |
| DECREASED URINE CONCENTRATION | **9** |
| ELEVATED LIVER ENZYMES | **9** |
| PANCREATITIS | **9** |
| ANXIETY | **8** |
| BLOOD IN VOMIT | **8** |
| DISORIENTATION | **8** |
| ELEVATED CREATININE | **8** |
| HYPOTHYROIDISM | **8** |
| LAMENESS | **8** |
| PR-LIVER, LESION(S) | **8** |

| | |
|---|---|
| PYODERMA | **8** |
| SELF TRAUMA | **8** |
| SKIN LESION NOS | **8** |
| WEAKNESS | **8** |
| ABNORMAL STOOL COLOURATION | **7** |
| BLOOD IN URINE | **7** |
| ELEVATED BUN | **7** |
| ELEVATED TOTAL BILIRUBIN | **7** |
| ERYTHEMA | **7** |
| HYPOALBUMINAEMIA | **7** |
| LYMPHOPENIA | **7** |
| NAUSEA | **7** |
| SKIN SCAB | **7** |
| THROMBOCYTOPENIA | **7** |
| AGGRESSION | **6** |
| AGITATION | **6** |
| BREATHING DIFFICULTY | **6** |
| CONJUNCTIVITIS | **6** |
| COUGH | **6** |
| DERMATITIS | **6** |
| ELEVATED LIPASE | **6** |
| EXCESSIVE THIRST | **6** |
| HEAD TILT | **6** |
| HYPERACTIVITY | **6** |
| LICKING | **6** |
| LOCALISED PAIN NOS | **6** |
| NYSTAGMUS | **6** |
| RELUCTANT TO MOVE | **6** |
| TREMOR | **6** |
| UNABLE TO STAND | **6** |

| | |
|---|---|
| URINE ABNORMALITIES NOS | **6** |
| ABDOMINAL DISCOMFORT | **5** |
| BACTERIAL SKIN INFECTION NOS | **5** |
| CRUST | **5** |
| DECREASED ACTIVITY | **5** |
| DERMAL THICKENING | **5** |
| GENERAL HAIR LOSS | **5** |
| HAIR COAT DISCOLOURATION | **5** |
| HAIR LOSS NOS | **5** |
| HYPERGLYCAEMIA | **5** |
| HYPOKALEMIC CONDITION | **5** |
| IMMUNE MEDIATED HAEMOLYTIC ANAEMIA | **5** |
| INCREASED RESPIRATORY RATE | **5** |
| LOCALISED HAIR LOSS | **5** |
| LOCALISED ITCHING | **5** |
| LOCALISED SKIN REACTION | **5** |
| MALAISE | **5** |
| MOIST DERMATITIS | **5** |
| PR-SKIN, LESION(S) | **5** |
| PUSTULES | **5** |
| SKIN DISORDERS NOS | **5** |
| SKIN IRRITATION | **5** |
| STUMBLING GAIT | **5** |
| URINARY INCONTINENCE | **5** |
| VESTIBULAR DISORDER NOS | **5** |
| ABNORMAL POSTURE NOS | **4** |
| ACCIDENTAL EXPOSURE | **4** |
| APPETITE LOSS | **4** |
| ASCITES | **4** |
| BILIRUBINURIA | **4** |

| | |
|---|---|
| BLINDNESS | **4** |
| BLOOD IN FAECES | **4** |
| COLLAPSE | **4** |
| CRYSTALLURIA | **4** |
| CULTURE/TITER DATA ABNORMAL | **4** |
| DECREASED BOWEL MOVEMENTS | **4** |
| DIGESTIVE TRACT DISORDER NOS | **4** |
| DRINKING A LOT | **4** |
| ENLARGED LIVER | **4** |
| FALLING | **4** |
| GASTRITIS | **4** |
| GASTROENTERITIS | **4** |
| HAEMATURIA | **4** |
| HAEMORRHAGIC GASTROENTERITIS | **4** |
| INCREASED APPETITE | **4** |
| INCREASED BOWEL MOVEMENTS (FREQUENCY) | **4** |
| LYMPHOMA | **4** |
| MELAENA | **4** |
| METASTATIC NEOPLASIA | **4** |
| MUCOUS STOOL | **4** |
| OVERDOSE | **4** |
| PAIN NOS | **4** |
| PARTIAL BLINDNESS | **4** |
| RENAL FAILURE | **4** |
| SHIVERING | **4** |
| SUDDEN DEATH | **4** |
| ALOPECIA | **3** |
| ALOPECIA LOCAL | **3** |
| CHLORIDE LOW, BLOOD | **3** |
| COLITIS | **3** |

| | |
|---|---|
| CONSTIPATION | **3** |
| CRYING | **3** |
| DECREASED RED BLOOD CELL COUNT | **3** |
| DERMAL MASS | **3** |
| DIABETES MELLITUS | **3** |
| DIGESTIVE TRACT NEOPLASM NOS | **3** |
| DISCOLOURED URINE | **3** |
| DRY SKIN | **3** |
| DULLNESS | **3** |
| ELEVATED AMYLASE | **3** |
| ELEVATED AST | **3** |
| ELEVATED GAMMA-GLUTAMYL TRANSFERASE (GGT) | **3** |
| EOSINOPHILIA | **3** |
| EPILEPTIC SEIZURE | **3** |
| EYE DISORDER NOS | **3** |
| FACIAL OEDEMA | **3** |
| FACIAL RASH | **3** |
| FEMALE REPRODUCTIVE TRACT DISORDER NOS | **3** |
| FOAMING AT THE MOUTH | **3** |
| GAGGING | **3** |
| GENERALISED RASH | **3** |
| GLAZED EYE | **3** |
| GLUCOSURIA | **3** |
| HAEMORRHAGIC DIARRHOEA | **3** |
| HAIR CHANGE | **3** |
| HEAD SHAKE | **3** |
| HEAD TREMOR | **3** |
| HEPATIC DISORDER NOS | **3** |
| HEPATITIS | **3** |
| HEPATOMEGALY | **3** |

| | |
|---|---|
| HEPATOPATHY | **3** |
| HOT SPOT (PYOTRAUMATIC DERMATITIS) | **3** |
| HYPERGLOBULINEMIA | **3** |
| HYPONATREMIA | **3** |
| HYPOPHOSPHATAEMIA | **3** |
| IMPAIRED VISION | **3** |
| INCREASED HEART RATE | **3** |
| LISTLESS | **3** |
| LOCAL SWELLING (NOT APPLICATION SITE) | **3** |
| LOCALISED OEDEMA (NOT APPLICATION SITE) | **3** |
| LOCALISED RASH | **3** |
| LUMP | **3** |
| LYMPHADENOPATHY | **3** |
| MONOCYTOSIS | **3** |
| MUSCLE SPASM NOS | **3** |
| MUSCULOSKELETAL PAIN | **3** |
| PACING | **3** |
| PAPULAR RASH | **3** |
| PAPULE | **3** |
| PERIORBITAL OEDEMA | **3** |
| PICA NOS | **3** |
| POLYPHAGIA | **3** |
| PROPRIOCEPTION DEFICIT | **3** |
| PROTEINURIA | **3** |
| PR-STOMACH, LESION(S) | **3** |
| RASH | **3** |
| REGENERATIVE ANAEMIA | **3** |
| REGURGITATION | **3** |
| RENAL DISORDER NOS | **3** |
| RESPIRATORY TRACT DISORDER NOS | **3** |

| | |
|---|---|
| SCOOTING | **3** |
| SLEEPINESS | **3** |
| SMALL LIVER | **3** |
| STAR-GAZING | **3** |
| STIFF GAIT | **3** |
| SWOLLEN LIP | **3** |
| TACHYCARDIA | **3** |
| TENESMUS | **3** |
| THROMBOCYTOSIS | **3** |
| TWITCHING | **3** |
| ULTRASOUND, LIVER ABNORMAL | **3** |
| URTICARIA | **3** |
| WBC, URINE | **3** |
| WELT | **3** |
| ABNORMAL BREATHING | **2** |
| ABNORMAL NECROPSY FINDING | **2** |
| ABNORMAL PUPIL LIGHT REFLEX | **2** |
| ACUTE RENAL FAILURE | **2** |
| ADRENAL GLAND DISORDER NOS | **2** |
| ALOPECIA GENERAL | **2** |
| ANAPHYLACTIC-TYPE REACTION | **2** |
| BALANCE IMPAIRED | **2** |
| BONE MARROW DISORDER NOS | **2** |
| BRADYCARDIA | **2** |
| BRUISING | **2** |
| BUN LOW, BLD | **2** |
| CARDIOMYOPATHY | **2** |
| CHOLELITHIASIS | **2** |
| CONFUSED | **2** |
| COPPER TOXICITY SIGNS | **2** |

| | |
|---|---|
| CORNEAL OEDEMA | **2** |
| DECREASED PACKED CELL VOLUME (PCV) | **2** |
| DROOPING EYELID | **2** |
| DRUG DISPENSING ERROR | **2** |
| DRUG DOSE ADMINISTRATION INTERVAL TOO SHORT | **2** |
| DULL | **2** |
| EAR IRRITATION | **2** |
| ELEVATED CHOLESTEROL (TOTAL) | **2** |
| ENTERITIS | **2** |
| EOSINOPENIA | **2** |
| EXCORIATION | **2** |
| EXERCISE INTOLERANCE | **2** |
| FACE AND NECK SWELLING | **2** |
| FLATULENCE, BLOATING AND DISTENSION | **2** |
| FOUND DEAD | **2** |
| FREQUENT URINATION | **2** |
| GENERAL ILLNESS | **2** |
| HAEMATEMESIS | **2** |
| HAEMOCONCENTRATION | **2** |
| HAEMORRHAGE NOS | **2** |
| HEAD PRESSING | **2** |
| HEART MURMUR | **2** |
| HIND LIMB PARALYSIS | **2** |
| HIND LIMB PARESIS | **2** |
| HYPERAESTHESIA | **2** |
| HYPERPHOSPHATAEMIA | **2** |
| HYPERPIGMENTATION | **2** |
| HYPERPROTEINAEMIA | **2** |
| HYPOPROTEINAEMIA | **2** |
| HYPOTHERMIA | **2** |

| | |
|---|---|
| INCORRECT DOSE ADMINISTERED | **2** |
| INCREASED SENSITIVITY TO SOUND | **2** |
| INCREASED SKIN SENSITIVITY | **2** |
| INTERNAL EAR DISORDER | **2** |
| INTESTINAL CONGESTION | **2** |
| IRON DEFICIENCY ANAEMIA | **2** |
| ISOSTHENURIA | **2** |
| ITCHY SKIN | **2** |
| LABOURED BREATHING | **2** |
| LACRIMATION | **2** |
| LENS DISORDER NOS | **2** |
| LIMPING | **2** |
| LIP LICKING | **2** |
| LIVER DISORDER NOS | **2** |
| LIVER FAILURE | **2** |
| LYMPHOCYTOSIS | **2** |
| MENTAL IMPAIRMENT NOS | **2** |
| MUSCLE SHAKING | **2** |
| MUSCLE TREMOR | **2** |
| MUSCLE WASTING | **2** |
| NASAL DISCHARGE | **2** |
| NEOPLASIA NOS | **2** |
| NERVOUS SYSTEM NEOPLASM | **2** |
| OCULAR DISCHARGE | **2** |
| ORAL BLEEDING | **2** |
| PINNAL ERYTHEMA | **2** |
| PINNAL OEDEMA | **2** |
| PLEURAL EFFUSION | **2** |
| PODODERMATITIS | **2** |
| PR-BRAIN, LESION(S) | **2** |

| | |
|---|---|
| PR-KIDNEY(S), LESION(S) | **2** |
| PR-LUNG(S), LESION(S) | **2** |
| PR-LYMPH NODE(S), LESION(S) | **2** |
| PROLONGED ACTIVATED PARTIAL THROMBIN TIME (APTT) | **2** |
| PROLONGED ONE STAGE PROTHROMBIN TIME (OSPT) | **2** |
| REDUCED RESPONSES | **2** |
| RIGIDITY | **2** |
| SKIN OEDEMA | **2** |
| SKIN SORE | **2** |
| SKIN WARMTH | **2** |
| SNEEZING | **2** |
| SPLENIC NEOPLASM | **2** |
| SPLENOMEGALY | **2** |
| STIFFNESS NOS | **2** |
| TARRY OR BLACK STOOL | **2** |
| TENSE ABDOMEN | **2** |
| TIREDNESS | **2** |
| TITER DATA ABNORMAL | **2** |
| TONIC-CLONIC SEIZURE | **2** |
| TRACHEITIS | **2** |
| UROLITHIASIS | **2** |
| VALVULAR INSUFFICIENCY | **2** |
| WEAKNESS OF LIMB | **2** |
| WHEEZING | **2** |
| ABDOMINAL CAVITY DISORDER NOS | **1** |
| ABDOMINAL EFFUSION | **1** |
| ABDOMINAL MASS | **1** |
| ABDOMINAL OEDEMA | **1** |
| ABNORMAL ECG | **1** |
| ABNORMAL MENACE REFLEX TEST | **1** |

| | |
|---|---|
| ABNORMAL MOVEMENT NOS | **1** |
| ABNORMAL RED BLOOD CELL | **1** |
| ABNORMAL URINE ODOUR | **1** |
| ALLERGIC PRURITUS | **1** |
| ALLERGIC SKIN REACTION | **1** |
| ALLERGY NOS | **1** |
| ANAL IRRITATION | **1** |
| ANAL SAC DISORDER | **1** |
| ANISOCORIA | **1** |
| ANTERIOR UVEITIS | **1** |
| ANURIA | **1** |
| ATOPIC ALLERGY NOS | **1** |
| AUTOIMMUNE DISORDER NOS | **1** |
| AZOTAEMIA | **1** |
| BLEPHAROSPASM | **1** |
| BLISTERING | **1** |
| BLOATED | **1** |
| BONE MARROW SUPPRESSION | **1** |
| BRAIN DISORDER NOS | **1** |
| BRONCHOPNEUMONIA | **1** |
| BRONCHOPULMONARY INFLAMMATION | **1** |
| BUMPING INTO WALLS | **1** |
| CARDIAC DISORDER NOS | **1** |
| CARDIAC ENLARGEMENT | **1** |
| CAT SCAN ABNORMAL | **1** |
| CATARACT | **1** |
| CENTRAL NERVOUS SYSTEM DISORDER NOS | **1** |
| CHATTERING OF TEETH | **1** |
| CHEWING | **1** |
| CHOLANGITIS | **1** |

| | |
|---|---|
| CIRRHOSIS | **1** |
| CLAW / HOOF / NAIL LOSS | **1** |
| CLOSED EYELID | **1** |
| COAGULOPATHY | **1** |
| COGNITIVE IMPAIRMENT | **1** |
| COLLAPSE NOS | **1** |
| COLLAPSE OF LEG | **1** |
| CONFUSION | **1** |
| CONGENITAL HEPATO-BILIARY DISORDER | **1** |
| CONVULSION | **1** |
| CREATININE LOW, BLOOD | **1** |
| CUSHINGS DISEASE - PITUITARY DEPENDENT | **1** |
| CYANOSIS | **1** |
| CYSTITIS | **1** |
| DEAFNESS | **1** |
| DECREASED HEART RATE | **1** |
| DECREASED PERCENTAGE OF RETICULOCYTES | **1** |
| DEPENDENT OEDEMA | **1** |
| DIABETES INSIPIDUS | **1** |
| DILATED PUPILS | **1** |
| DISCOLOURED TEETH | **1** |
| DISCOMFORT NOS | **1** |
| DISORIENTED STATE | **1** |
| DISTENSION OF ABDOMEN | **1** |
| DRUG DOSE ADMINISTRATION INTERVAL TOO LONG | **1** |
| DRUNKEN GAIT | **1** |
| DRY MOUTH | **1** |
| DYSPHAGIA | **1** |
| DYSPNOEA | **1** |
| DYSURIA | **1** |

| | |
|---|---|
| ECCHYMOSIS | **1** |
| ELEVATED CREATININE-KINASE (CK) | **1** |
| ELEVATED RENAL PARAMETERS | **1** |
| ELEVATED TEMPERATURE | **1** |
| ELEVATED TRIGLYCERIDE | **1** |
| ENDOCRINE NEOPLASM | **1** |
| EPISTAXIS | **1** |
| ERUPTION | **1** |
| ERYTHEMA MULTIFORME | **1** |
| ERYTHEMATOUS RASH | **1** |
| EXCESS TEAR FLOW | **1** |
| EXOPHTHALMIA | **1** |
| EYE INFLAMMATION NOS | **1** |
| EYE REDNESS | **1** |
| EYELID INFLAMMATION | **1** |
| EYELID OEDEMA | **1** |
| FACIAL NERVE DISORDER | **1** |
| FACIAL PARALYSIS | **1** |
| FAECAL IMPACTION | **1** |
| FAECAL INCONTINENCE | **1** |
| FASCICULATION | **1** |
| FEBRILE | **1** |
| FLUID IN ABDOMEN NOS | **1** |
| FLY BITING BEHAVIOUR | **1** |
| GAIT ABNORMALITY | **1** |
| GALL BLADDER & BILE DUCT DISORDER NOS | **1** |
| GASTRIC BLOAT | **1** |
| GASTRIC DISTENSION | **1** |
| GASTRIC IRRITATION | **1** |
| GASTRIC ULCERATION NOS | **1** |

| | |
|---|---|
| GENERALISED WEAKNESS | **1** |
| GLAUCOMA | **1** |
| HAEMANGIOSARCOMA | **1** |
| HAEMOGLOBINURIA | **1** |
| HAEMOLYSIS | **1** |
| HALITOSIS | **1** |
| HEAD BOBBING | **1** |
| HEAD DOWN | **1** |
| HEARING DECREASED | **1** |
| HEART VALVE DISORDER | **1** |
| HEMATOCRIT(HCT) HIGH, BLOOD | **1** |
| HEPATIC FIBROSIS | **1** |
| HEPATIC NECROSIS | **1** |
| HEPATO-BILIARY DISORDER NOS | **1** |
| HIND LIMB ATAXIA | **1** |
| HYPERALBUMINAEMIA | **1** |
| HYPERCALCAEMIC CONDITION | **1** |
| HYPERKALEMIC CONDITION | **1** |
| HYPERSENSITIVITY TO PAIN | **1** |
| HYPERTENSION | **1** |
| HYPERTHERMIA | **1** |
| HYPOADRENOCORTICISM | **1** |
| HYPOSENSITIVITY TO PAIN | **1** |
| IMMUNE MEDIATED THROMBOCYTOPENIA | **1** |
| IMPAIRED PROPRIOCEPTION | **1** |
| INAPPROPRIATE SCHEDULE OF DRUG ADMINISTRATION | **1** |
| INCREASED BORBORYGMUS | **1** |
| INCREASED REFLEXES | **1** |
| INCREASED SALIVATION | **1** |
| INCREASED YAWNING | **1** |

| | |
|---|---|
| INJECTED SCLERA | **1** |
| INTESTINAL DISORDER NOS | **1** |
| INTESTINAL HAEMORRHAGE | **1** |
| INTESTINAL PERFORATION | **1** |
| INVOLUNTARY DEFECATION | **1** |
| JOINT SWELLING | **1** |
| LACK OF COORDINATION | **1** |
| LATERAL RECUMBENCY | **1** |
| LENS LUXATION | **1** |
| LEUCOPENIA | **1** |
| LIMB WEAKNESS | **1** |
| LIP ERYTHEMA | **1** |
| LIP OEDEMA | **1** |
| LIVER DEGENERATION | **1** |
| LOW BLOOD PRESSURE | **1** |
| LOW PLATELET COUNT | **1** |
| LUMBAR PAIN | **1** |
| LUNG OEDEMA | **1** |
| LUNG SOUND | **1** |
| LUNG TUMOUR | **1** |
| MAMMARY GLAND DISORDER NOS | **1** |
| MENINGITIS | **1** |
| MICROORGANISMS, URINE | **1** |
| MILIARY DERMATITIS | **1** |
| MIOSIS | **1** |
| MUCUS IN EYE | **1** |
| MUSCLE PAIN | **1** |
| MUSCLE STIFFNESS | **1** |
| MUSCULOSKELETAL DISORDER NOS | **1** |
| MYDRIASIS | **1** |

| | |
|---|---|
| NASAL CAVITY AND SINUS DISORDER NOS | **1** |
| NASAL CONGESTION | **1** |
| NEPHROPATHY | **1** |
| NEUROLOGICAL SIGNS NOS | **1** |
| NEUROLOGICAL SYMPTOMS NOS | **1** |
| NEUTROPENIA | **1** |
| NON-REGENERATIVE ANAEMIA | **1** |
| NT - HAEMORRHAGIC ENTERITIS | **1** |
| NT - HYPERTROPHIC DILATED CARDIOMYOPATHY | **1** |
| NT - NECROTIC HEPATITIS | **1** |
| OEDEMA OF THE EXTREMITIES | **1** |
| OEDEMATOUS ERYTHEMA | **1** |
| OPISTHOTONUS | **1** |
| ORAL ABSCESS | **1** |
| ORAL CAVITY DISORDER NOS | **1** |
| ORAL ERYTHEMA | **1** |
| ORAL ULCERATION | **1** |
| OTITIS INTERNA | **1** |
| OTITIS MEDIA | **1** |
| OTITIS NOS | **1** |
| PALPABLE MASS NOS | **1** |
| PANCREAS DISORDER | **1** |
| PANCREATIC ENZYMES HIGH, BLOOD | **1** |
| PARALYSIS NOS | **1** |
| PARAPHIMOSIS | **1** |
| PERITONITIS | **1** |
| PINNAL IRRITATION | **1** |
| PINNAL REDDENING | **1** |
| PITUITARY DISORDER NOS | **1** |
| POLLAKIURIA | **1** |

| | |
|---|---|
| POOR COAT CONDITION | **1** |
| PR-CEREBRUM, LESION(S) | **1** |
| PR-HEART, LESION(S) | **1** |
| PR-MOUTH/LIP(S), LESION(S) | **1** |
| PROFUSE BLEEDING | **1** |
| PROSTATE HYPERTROPHY | **1** |
| PR-SMALL INTESTINE, LESION(S) | **1** |
| PR-SPINAL CORD, LESION(S) | **1** |
| PR-SPLEEN, LESION(S) | **1** |
| PR-THYROID, LESION(S) | **1** |
| PTYALISM | **1** |
| PULMONARY CONGESTION | **1** |
| PUPIL DISORDER | **1** |
| RECTAL BLEEDING | **1** |
| RECTAL HAEMORRHAGE | **1** |
| RED BLOOD CELL DISORDER | **1** |
| RED MUCOSAE | **1** |
| RESPIRATORY DISTRESS | **1** |
| RESPIRATORY SIGNS | **1** |
| RESPIRATORY SOUND | **1** |
| RETICULOCYTOSIS | **1** |
| RETINAL DEGENERATION | **1** |
| RETINAL DISORDER NOS | **1** |
| SCALE | **1** |
| SEDATION | **1** |
| SELF MUTILATION | **1** |
| SKIN PETECHIAE | **1** |
| SKIN SWELLING | **1** |
| SMELLY BREATH | **1** |
| SPLEEN AND RETICULO-ENDOTHELIAL SYSTEM DISORDER NOS | **1** |

| | |
|---|---|
| SPLEEN HYPERTROPHY | **1** |
| SPONDYLOSIS | **1** |
| SQUINTING | **1** |
| STAGGERING | **1** |
| STIFFNESS LIMB | **1** |
| STOMACH INFLAMMATION | **1** |
| STRAINING TO DEFECATE | **1** |
| STRANGURIA | **1** |
| SUSPECTED INFECTIOUS AGENT TRANSMISSION | **1** |
| SWALLOWING DIFFICULT | **1** |
| SWELLING AROUND EYE | **1** |
| SWOLLEN EYE | **1** |
| SWOLLEN LYMPH NODE | **1** |
| SWOLLEN TONGUE | **1** |
| SYMPTOM NOS INVOLVING NEUROLOGICAL AND MUSCULAR SKELETAL SOCS | **1** |
| SYNCOPE | **1** |
| TEETH GRINDING | **1** |
| TEMPORARY BLINDNESS | **1** |
| THYROID GLAND DISORDER NOS | **1** |
| TONGUE ULCERATION | **1** |
| TOOTH DISORDER | **1** |
| TRACHEAL AND LARYNGEAL DISORDER NOS | **1** |
| TREMOR OF LIMB | **1** |
| TRIGEMINUS PARALYSIS | **1** |
| ULCERATIVE DERMATITIS | **1** |
| UNABLE TO JUMP | **1** |
| UNEXPLAINED DEATH | **1** |
| UNPALATABLE | **1** |
| UNRELATED DEATH | **1** |
| UNRESPONSIVE TO STIMULI | **1** |

| | |
|---|---|
| URINARY TENESMUS | 1 |
| URINARY TRACT DISORDER NOS | 1 |
| URINATION | 1 |
| URINE LEAKAGE | 1 |
| VAGINAL HAEMORRHAGE | 1 |
| VENTRICULAR ARRHYTHMIA | 1 |
| WEAK PULSE | 1 |
| WEIGHT GAIN | 1 |
| WHEAL | 1 |

Species: Dog
Route of Administration: SUBCUTANEOUS

| Sign : | Number of Times Reported : |
|---|---|
| ALKALINE URINE | 1 |
| ANOREXIA | 1 |
| DEATH | 1 |
| ELEVATED ALT | 1 |
| ELEVATED SAP | 1 |
| ELEVATED TOTAL BILIRUBIN | 1 |
| FEVER | 1 |
| HEPATIC NECROSIS | 1 |
| INTESTINAL HAEMORRHAGE | 1 |
| PR-LIVER, LESION(S) | 1 |
| PR-SMALL INTESTINE, LESION(S) | 1 |
| VOMITING | 1 |

Species: Dog
Route of Administration: TOPICAL

| Sign : | Number of Times Reported : |
|---|---|
| PRURITUS | 1 |
| VOMITING | 1 |

Species: Dog
Route of Administration: UNKNOWN

| Sign : | Number of Times Reported : |
|---|---|

| | |
|---|---|
| APPETITE LOSS | 1 |
| CONVULSION | 1 |
| INEFFECTIVE, FLEAS | 1 |

Species: Human
Route of Administration: ORAL

| Sign : | Number of Times Reported : |
|---|---|
| ABNORMAL BREATHING | 1 |
| NUMBNESS | 1 |

Species: Human
Route of Administration: TOPICAL

| Sign : | Number of Times Reported : |
|---|---|
| SWOLLEN LIP | 1 |

Species: Human
Route of Administration: UNKNOWN

| Sign : | Number of Times Reported : |
|---|---|
| NAUSEA | 1 |
| RASH | 1 |

Species: Wolf
Route of Administration: ORAL

| Sign : | Number of Times Reported : |
|---|---|
| ANXIETY | 1 |
| INCREASED APPETITE | 1 |