

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 1/11/2016. The search parameters were:

Active ingredient(s): afoxolaner; fluralaner
Reports received: From 6/18/2015 through 1/6/2016
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. Afoxolaner was approved by FDA on 9/24/2013 and fluralaner was approved by FDA on 5/15/2014. For the time period of the ADE database search (6/18/2015 – 1/6/2016), there were a total of 2,048 ADE reports received for afoxolaner for dogs, and a total of 2,852 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 : 18-Jun-2015 -thru- 06-Jan-2016
For case type: Spontaneous

DRUG: FLURALANER

Species: **Cat**
Route of Administration: **ORAL**

Sign :	Number of Times Reported :
BALANCE IMPAIRED	1
DIARRHOEA	1
LACK OF EFFICACY	1
RESPIRATORY SIGNS	1
VOMITING	1

Species: **Dog**
Route of Administration: **INTRA-UTERINE**

Sign :	Number of Times Reported :
CONGENITAL CARDIOVASCULAR DISORDER NOS	1
CONGENITAL REPRODUCTIVE TRACT DISORDER NOS	1
CRYPTORCHIDISM	1
HEART MURMUR	1

Species: **Dog**
Route of Administration: **MISSING**

Sign :	Number of Times Reported :
LETHARGY	3
VOMITING	3
ABNORMAL TEST RESULT	2
ANOREXIA	2
ABNORMAL RADIOGRAPH FINDING	1
BLOODY DIARRHOEA	1
CONSTIPATION	1

DECREASED APPETITE	1
DERMATITIS	1
DIARRHOEA	1
DIGESTIVE TRACT DISORDER NOS	1
DISORIENTATION	1
DRUG DOSE ADMINISTRATION INTERVAL TOO SHORT	1
ELEVATED BUN	1
ELEVATED CREATININE	1
EMESIS (MULTIPLE)	1
EXCESSIVE LICKING AND/OR GROOMING	1
FLATULENCE	1
FREQUENT URINATION	1
HYPERCALCAEMIA	1
HYPOKALEAEMIA	1
HYPOPARATHYROIDISM	1
INEFFECTIVE, FLEAS	1
LEUCOPENIA	1
LYMPHOMA	1
LYMPHOPENIA	1
PIGMENTATION DISORDER	1
POLYURIA	1
RETCHING	1
SWALLOWING DIFFICULT	1
TENESMUS	1
TONGUE DISORDER NOS	1
URINE ABNORMALITIES NOS	1
WEIGHT LOSS	1

Species: Dog
Route of Administration: ORAL

Sign :	Number of Times Reported :
VOMITING	1,221

LETHARGY	349
DIARRHOEA	241
EMESIS (MULTIPLE)	157
ANOREXIA	150
PRURITUS	120
ABNORMAL TEST RESULT	102
DECREASED APPETITE	77
SEIZURE NOS	76
LACK OF EFFICACY	65
BEHAVIOURAL DISORDER NOS	59
POLYDIPSIA	59
WEIGHT LOSS	56
POLYURIA	50
DEATH	49
LOOSE STOOL	48
BLOODY DIARRHOEA	45
INEFFECTIVE, FLEAS	44
ELEVATED ALT	42
ELEVATED SAP	41
INAPPETENCE	40
ALLERGIC REACTION	39
DEATH BY EUTHANASIA	38
NOT EATING	38
LACK OF EFFICACY (ECTOPARASITES)	37
SCRATCHING	37
HIVES	36
SHAKING	35
ERYTHEMA	31
ELEVATED BUN	30
ABNORMAL RADIOGRAPH FINDING	29

ELEVATED CREATININE	29
LEUCOCYTOSIS	29
PANTING	29
VOCALISATION	27
INAPPROPRIATE URINATION	26
FEVER	24
DEHYDRATION	23
ABNORMAL ULTRASOUND FINDING	22
ANAEMIA NOS	22
DEPRESSION	22
PICA NOS	22
WEAKNESS	22
ITCHING	21
ELEVATED LIVER ENZYMES	20
ELEVATED TOTAL BILIRUBIN	20
THROMBOCYTOPENIA	20
HIDING	19
HYPERPHOSPHATAEMIA	19
FLATULENCE	18
MUCOUS STOOL	18
ATAXIA	17
ALOPECIA LOCAL	16
LOCALISED PAIN NOS	16
RESTLESSNESS	16
DISORIENTATION	15
ELEVATED GAMMA-GLUTAMYL TRANSFERASE (GGT)	15
HAIR LOSS NOS	15
HYPOALBUMINAEMIA	15
NOT DRINKING	15
URINARY TRACT INFECTION	15

COUGH	14
HYPERGLYCAEMIA	14
NAUSEA	14
NEUTROPHILIA	14
SKIN SCAB	14
ABDOMINAL PAIN	13
ANXIETY	13
EMESIS	13
INEFFECTIVE, TICKS	13
TREMBLING	13
TREMOR	13
DECREASED ACTIVITY	12
DECREASED URINE CONCENTRATION	12
EXCESSIVE THIRST	12
FACIAL SWELLING	12
PALE MUCOUS MEMBRANE	12
PANCREATITIS	12
RELUCTANT TO MOVE	12
RETCHING	12
SKIN LESION NOS	12
ABNORMAL BREATHING	11
BLINDNESS	11
DROOLING	11
HOT SPOT (PYOTRAUMATIC DERMATITIS)	11
HYPERACTIVITY	11
HYPOPROTEINAEMIA	11
INAPPROPRIATE DEFECATION	11
MONOCYTOSIS	11
REDDENING OF THE SKIN	11
SKIN DISORDERS NOS	11

BLOOD IN VOMIT	10
COLLAPSE	10
DERMATITIS	10
HYPERSALIVATION	10
HYPOGLYCAEMIA	10
LABOURED BREATHING	10
PROTEINURIA	10
WALKING DIFFICULTY	10
ABNORMAL STOOL COLOURATION	9
BLOOD IN FAECES	9
CRUST	9
DECREASED PACKED CELL VOLUME (PCV)	9
ELEVATED AMYLASE	9
GALL BLADDER & BILE DUCT DISORDER NOS	9
HYPOTHYROIDISM	9
LYMPHOPENIA	9
PUSTULES	9
PYODERMA	9
TWITCHING	9
ADIPSIA	8
BILIRUBINURIA	8
DECREASED HAEMOGLOBIN	8
DECREASED RED BLOOD CELL COUNT	8
ELEVATED AST	8
ELEVATED CHOLESTEROL (TOTAL)	8
ERYTHEMATOUS RASH	8
FALLING	8
GAIT ABNORMALITY	8
GENERAL HAIR LOSS	8
HAEMATURIA	8

HYPOCALCAEMIC CONDITION	8
LISTLESS	8
LIVER DISORDER NOS	8
RASH	8
RENAL FAILURE	8
TACHYCARDIA	8
ABNORMAL NECROPSY FINDING	7
ALOPECIA	7
BREATHING DIFFICULTY	7
DISTENSION OF ABDOMEN	7
DRINKING A LOT	7
DRY SKIN	7
FLAKING SKIN	7
GENERAL PAIN	7
GENERALISED ITCHING	7
HYPOTHERMIA	7
LIMB WEAKNESS	7
LOCALISED HAIR LOSS	7
LOCALISED ITCHING	7
LOCALISED RASH	7
MUSCULOSKELETAL DISORDER NOS	7
PR-LIVER, LESION(S)	7
SHIVERING	7
SLEEPINESS	7
THROMBOCYTOSIS	7
AGGRESSION	6
BACTERIAL SKIN INFECTION NOS	6
CIRCLING	6
CONSTIPATION	6
DIABETES MELLITUS	6

ELEVATED LIPASE	6
EXCESSIVE LICKING AND/OR GROOMING	6
FREQUENT URINATION	6
HYPERCALCAEMIA	6
INTESTINAL DISORDER NOS	6
LICKING	6
LYMPHOMA	6
OCULAR DISCHARGE	6
PACING	6
STUMBLING GAIT	6
SUDDEN DEATH	6
TACHYPNOEA	6
TENESMUS	6
ABDOMINAL DISCOMFORT	5
ABNORMAL PUPIL LIGHT REFLEX	5
AGITATION	5
ALOPECIA GENERAL	5
BLOOD IN URINE	5
BONE AND JOINT DISORDER NOS	5
CRYING	5
CRYSTALLURIA	5
DECREASED CHOLESTEROL (TOTAL)	5
DECREASED DRINKING	5
DRUG DOSE ADMINISTRATION INTERVAL TOO SHORT	5
GENERALISED WEAKNESS	5
HIND LIMB ATAXIA	5
HYPERGLOBULINEMIA	5
HYPOKALEAEMIA	5
ICTERUS	5
IMMUNE MEDIATED THROMBOCYTOPENIA	5

LIMPING	5
LOW PLATELET COUNT	5
MELAENA	5
OTITIS EXTERNA	5
PAPULAR RASH	5
PAPULE	5
PROPRIOCEPTION DEFICIT	5
PR-SKIN, LESION(S)	5
PYURIA	5
SELF TRAUMA	5
SKIN SORE	5
SPLENOMEGALY	5
STAGGERING	5
STIFFNESS NOS	5
STILLBIRTH	5
TARRY OR BLACK STOOL	5
TIREDNESS	5
WEAKNESS OF LIMB	5
ABNORMAL MENACE REFLEX TEST	4
ANAL SAC DISORDER	4
BLOODSHOT EYE	4
BRUISING	4
BUN LOW, BLD	4
CHEWING	4
CHRONIC RENAL FAILURE	4
DERMAL MASS	4
DIGESTIVE TRACT DISORDER NOS	4
DILATED PUPILS	4
ELEVATED CREATININE-KINASE (CK)	4
ELEVATED RENAL PARAMETERS	4

ENLARGED LIVER	4
ENTERITIS	4
EOSINOPHILIA	4
EXCORIATION	4
EYE REDNESS	4
FLUID IN ABDOMEN NOS	4
GENERAL ILLNESS	4
GLAZED EYE	4
HIND LIMB PARESIS	4
HYPONATREMIA	4
IMMUNE MEDIATED HAEMOLYTIC ANAEMIA	4
INCREASED BORBORYGMUS	4
INFERTILITY NOS	4
LEUCOPENIA	4
LIVER FAILURE	4
LOCAL SWELLING (NOT APPLICATION SITE)	4
LYMPHOCYTOSIS	4
MALAISE	4
MISCELLANEOUS EATING DISORDER NOS	4
MOIST DERMATITIS	4
NOT SLEEPING	4
PANCREAS DISORDER	4
PLEURAL EFFUSION	4
REGURGITATION	4
RESPIRATORY ARREST	4
SKIN IRRITATION	4
TITER DATA ABNORMAL	4
TREMOR OF LIMB	4
UNRESPONSIVE TO STIMULI	4
URINARY INCONTINENCE	4

ABNORMAL POSTURE NOS	3
ABNORMAL RED BLOOD CELL	3
ACUTE RENAL FAILURE	3
APPETITE LOSS	3
ARRHYTHMIA	3
ATOPIC ALLERGY NOS	3
AZOTAEMIA	3
BALANCE PROBLEM	3
BIRTH DEFECT	3
BLISTERING	3
BRADYCARDIA	3
CARDIAC ARREST	3
CULTURE/TITER DATA ABNORMAL	3
CYSTITIS	3
DISCOLOURED URINE	3
DISORDER OF RED BLOOD CELL NOS	3
DROOPING EYELID	3
DRY MUCOUS MEMBRANE	3
DULLNESS	3
EYE DISORDER NOS	3
FOAMING AT THE MOUTH	3
GASTROENTERITIS	3
GENERALISED RASH	3
HAEMORRHAGIC GASTROENTERITIS	3
HAIR SHEDDING	3
HEAD SHAKE - EAR DISORDER	3
HEAD TREMOR	3
HEART MURMUR	3
HYPERKALEMIC CONDITION	3
HYPERPROTEINAEMIA	3

HYPOGLOBULINEMIA	3
HYPOKALEMIC CONDITION	3
HYPOMAGNESAEMIC CONDITION	3
HYPOSTHENURIA	3
INCREASED APPETITE	3
INCREASED BOWEL MOVEMENTS (FREQUENCY)	3
INCREASED RESPIRATORY RATE	3
JAUNDICE	3
LAMENESS	3
LIP LICKING	3
LYMPHADENOPATHY	3
MUSCLE SPASM NOS	3
MUSCLE WASTING	3
MYDRIASIS	3
NASAL BLEEDING	3
NYSTAGMUS	3
OTITIS NOS	3
PALLOR	3
PNEUMONIA	3
POOR COAT CONDITION	3
PR-LUNG(S), LESION(S)	3
PRURITIC RASH	3
RECUMBENCY	3
REDUCED RESPONSES	3
REGENERATIVE ANAEMIA	3
RENAL DISORDER NOS	3
SEDATION	3
SKIN INFLAMMATION NOS	3
SMALL LIVER	3
SPLENIC NEOPLASM	3

STOMACH UPSET	3
ULTRASOUND, LIVER ABNORMAL	3
UNABLE TO RISE	3
UNABLE TO STAND	3
UNCOMFORTABLE	3
UNSTEADY GAIT	3
URINE ABNORMALITIES NOS	3
URTICARIA	3
URTICARIAL ERYTHEMA	3
WEIGHT GAIN	3
WELT	3
ABDOMINAL CAVITY HAEMORRHAGE	2
ABDOMINAL EFFUSION	2
ABNORMAL SPERMATOZOA	2
ACIDIC URINE	2
ACIDOSIS	2
ALBUMIN/GLOBULIN RATIO LO, BLD	2
ALLERGIC DERMATITIS	2
ALLERGIC PRURITUS	2
ALLERGIC SKIN REACTION	2
ASCITES	2
BARKING	2
CARDIAC DISORDER NOS	2
CATARACT	2
CHOLANGIOHEPATITIS	2
CHRONIC PANCREATITIS	2
COLITIS	2
CONFUSION	2
CONVULSION	2
CORNEAL OEDEMA	2

DECREASED NUMBER OF SPERMATOZOA	2
DENTAL CALCULUS	2
DEVITALISATION	2
DISCOMFORT NOS	2
DISORIENTED STATE	2
DRUG DOSE ADMINISTRATION INTERVAL TOO LONG	2
DYSPNOEA	2
EAR IRRITATION	2
ECCHYMOSIS	2
ELECTROLYTE DISORDER	2
ELEVATED BILE ACIDS	2
ELEVATED LACTIC ACID DEHYDROGENASE (LDH)	2
ENLARGED KIDNEY(S)	2
ENLARGED LYMPH NODE	2
EOSINOPENIA	2
EPILEPTIC SEIZURE	2
EPISTAXIS	2
EYELID ERYTHEMA	2
EYELID LUMP	2
FOUND DEAD	2
FUNGAL SKIN INFECTION NOS	2
GAGGING	2
GASTRIC ULCERATION NOS	2
GASTRITIS	2
GENERALISED SKIN REACTION	2
GLUCOSURIA	2
HAEMANGIOSARCOMA	2
HAEMOCONCENTRATION	2
HAEMOLYTIC ANAEMIA	2
HAEMORRHAGE NOS	2

HAIR CHANGE	2
HALLUCINATION	2
HEAD SHAKE	2
HEAD SHAKE - BEHAVIOURAL DISORDER	2
HEAD TILT	2
HEAT STROKE	2
HEPATIC CIRRHOSIS	2
HEPATIC NEOPLASM	2
HEPATITIS	2
HYPERAEMIA	2
HYPERCALCAEMIC CONDITION	2
HYPERKERATOSIS	2
HYPERTHERMIA	2
HYPOTENSION	2
INCREASED PERCENTAGE RETICULOCYTES	2
INCREASED SALIVATION	2
INEFFECTIVE, DEMODEX MITES	2
INJECTED SCLERA	2
INTESTINAL OCCLUSION	2
INVOLUNTARY DEFECATION	2
ISOSTHENURIA	2
ITCHY RASH	2
LATERAL RECUMBENCY	2
LIMPNESS	2
LIP OEDEMA	2
LIPOMA	2
LOSS OF SMELL	2
LOSS OF VISION	2
LUNG COLLAPSE	2
MUSCULOSKELETAL PAIN	2

MYOSITIS	2
NASAL CONGESTION	2
NASAL DISCHARGE	2
NEUROLOGICAL SIGNS NOS	2
NEUROPATHY NOS	2
NT - HEPATIC LIPIDOSIS (STEATOSIS)	2
OPEN MOUTH BREATHING	2
ORAL BLEEDING	2
OTHER EAR DISORDER NOS	2
PARTIAL DEAFNESS	2
PEMPHIGUS FOLIACEUS	2
PETECHIAE NOS	2
PIMPLES	2
PINNAL OEDEMA	2
PINNAL REDDENING	2
PODODERMATITIS	2
POLYPHAGIA	2
PREMATURE BIRTH	2
PR-PANCREAS, LESION(S)	2
PR-STOMACH, LESION(S)	2
PTYALISM	2
PULMONARY DISORDER NOS	2
PYOMETRA	2
RED BLOOD CELLS(RBC) ABNORMAL	2
RESPIRATORY DISTRESS	2
RETINAL DEGENERATION	2
REVERSE SNEEZING	2
RIGIDITY	2
ROLLING	2
RUBBING	2

SCOOTING	2
SEPTICAEMIA	2
SKIN HYPERAEMIA	2
SKIN SCRAPING ABNORMAL	2
SNEEZING	2
STAR-GAZING	2
STOMATITIS	2
SWELLING AROUND EYE	2
SWOLLEN LYMPH NODE	2
TONGUE PROTRUSION	2
TONIC SEIZURE	2
TRAUMA NOS	2
ULCERATIVE DERMATITIS	2
UNEXPLAINED DEATH	2
URINARY BLADDER DISORDER NOS	2
URINE LEAKAGE	2
UROLITHIASIS	2
VAGINAL DISCHARGE	2
VAGINAL HAEMORRHAGE	2
WEAK PULSE	2
WHEEZING	2
ABDOMINAL CAVITY DISORDER NOS	1
ABDOMINAL MASS	1
ABNORMAL MOVEMENT NOS	1
ABNORMAL NUMBER OF OFFSPRING	1
ABNORMAL VISION	1
ABSCESS NOS	1
ALBUMIN/GLOBULIN RATIO HI, BLD	1
ALKALINE URINE	1
ANAL OEDEMA	1

ANAPHYLACTIC-TYPE REACTION	1
ANAPHYLAXIS	1
ANISOCORIA	1
ANURIA	1
APPLICATION SITE PRURITUS	1
APPLICATION SITE REDDENING	1
APPLICATION SITE SCRATCHING	1
ARCHED BACK	1
ARTHRITIS	1
AUTOIMMUNE DISORDER NOS	1
BALANCE IMPAIRED	1
BANDS(NEUTROPHILS) HIGH, BLOOD	1
BELCHING	1
BLINKING	1
BLOATED STOMACH	1
BREATHLESSNESS	1
BRONCHITIS	1
BRONCHOPNEUMONIA	1
BUMPING INTO WALLS	1
BURN	1
CARDIAC ENLARGEMENT	1
CENTRAL NERVOUS SYSTEM DEPRESSION	1
CENTRAL NERVOUS SYSTEM DISORDER NOS	1
CEREBROSPINAL FLUID ABNORMAL	1
CHANGE IN BLOOD PROTEIN NOS	1
CHAPPED SKIN	1
CHATTERING OF TEETH	1
CHLORIDE LOW, BLOOD	1
CIRCULATORY SHOCK	1
CLOUDY EYE	1

COAGULOPATHY	1
COGNITIVE IMPAIRMENT	1
COLD FEELING OF EXTREMITY	1
COLLAPSE NOS	1
COLLAPSE OF LEG	1
CONGENITAL DISORDER NOS	1
CONGESTIVE HEART FAILURE	1
CONJUNCTIVITIS	1
CONSTRICTED PUPILS	1
COUGH, PRODUCTIVE	1
CREATININE LOW, BLOOD	1
CUSHINGS DISEASE NOS	1
CUTANEOUS NECROSIS	1
DECREASED BOWEL MOVEMENTS	1
DENTAL DISEASE	1
DENTAL PLAQUE	1
DEPIGMENTATION OF NASAL PLANE	1
DERMAL CYST(S)	1
DERMAL THICKENING	1
DIABETES	1
DIGESTIVE TRACT NEOPLASM NOS	1
DILATED RENAL PELVIS	1
DRY MOUTH	1
DRY NOSE	1
DULL	1
DUODENITIS	1
DYSTOCIA	1
EAR FLAPPING/TWITCHING	1
EAR INFECTION NOS	1
ELEVATED TEMPERATURE	1

ELEVATED TRIGLYCERIDE	1
ENDOCRINE NEOPLASM	1
ENLARGED LYMPH NODE(S)	1
EPIDERMAL COLLARETTE	1
EQUILIBRIUM DISORDER	1
ERYTHEMA MULTIFORME	1
EXCESSIVE SWEATING	1
EXERCISE INTOLERANCE	1
EXOCRINE PANCREATIC INSUFFICIENCY	1
EXOPHTHALMIA	1
EYE IRRITATION	1
EYE ITCHING	1
EYE PAIN	1
EYES ROLLING BACK	1
FACE AND NECK SWELLING	1
FACIAL NERVE DISORDER	1
FAECAL INCONTINENCE	1
FASCICULATION	1
FATTY LIVER	1
FLATULENCE, BLOATING AND DISTENSION	1
FLY BITING BEHAVIOUR	1
FOLLICULITIS	1
FOOD REFUSAL	1
FRACTURE	1
GALL BLADDER INFLAMMATION	1
GASTRIC ULCER	1
GENITAL TRACT LICKING	1
GINGIVAL DISORDER	1
GINGIVAL ERYTHEMA	1
GINGIVAL SWELLING	1

GINGIVITIS	1
GREASY SKIN	1
GROANING	1
GUT SOUNDS INCREASED	1
HAEMATEMESIS	1
HAEMATOCHEDIA	1
HAEMOLYSIS	1
HAEMORRHAGIC DIARRHOEA	1
HAIR COAT DISCOLOURATION	1
HEAD PRESSING	1
HEART FAILURE	1
HEART VALVE DISORDER	1
HEMATOCRIT(HCT) HIGH, BLOOD	1
HEMIPLEGIA	1
HEMOGLOBIN(HB) HIGH, BLOOD	1
HEPATIC DISORDER NOS	1
HEPATIC FAILURE	1
HEPATIC FIBROSIS	1
HEPATIC NECROSIS	1
HEPATO-BILIARY DISORDER NOS	1
HEPATOMEGALY	1
HICCUP	1
HORNER'S SYNDROME	1
HYPERAEMIC MUCOUS MEMBRANE	1
HYPERALBUMINAEMIA	1
HYPEREXCITATION	1
HYPERMETRIA	1
HYPERNATREMIA	1
HYPERSENSITIVITY REACTION	1
HYPERTRICHOSIS	1

HYPERVENTILATION	1
HYPOPARATHYROIDISM	1
HYPOPHOSPHATAEMIA	1
ILEITIS	1
ILEUS	1
IMPAIRED CONSCIOUSNESS	1
INCOORDINATION	1
INCREASED COAGULATION TIME	1
INCREASED HEART RATE	1
INCREASED INTRA-OCULAR PRESSURE	1
INCREASED LUNG SOUNDS	1
INCREASED URINE CONCENTRATION	1
INEFFECTIVE, LOSS OF EFFECT	1
INTENTION TREMOR	1
INTESTINAL CONGESTION	1
IRREGULAR BREATHING	1
ITCHY SKIN	1
JOINT INFLAMMATION	1
JOINT PAIN	1
JOINT PAIN NOS	1
JOINT SWELLING	1
LENS DISORDER NOS	1
LICK GRANULOMA	1
LIP DISORDER NOS	1
LIPAEMIA	1
LIVER FIBROSIS	1
LIVER TUMOUR	1
LOCALISED OEDEMA (NOT APPLICATION SITE)	1
LOCALISED SKIN REACTION	1
LOOSE BOWEL	1

LOSS OF CONSCIOUSNESS	1
LOW BLOOD PRESSURE	1
LOW VISION	1
LUMBAR PAIN	1
LUMP	1
LUNG SOUND	1
MAMMARY GLAND NEOPLASM NOS	1
MENTAL IMPAIRMENT NOS	1
MILIARY DERMATITIS	1
MONOCYTOPENIA	1
MOTOR DYSFUNCTION NOS	1
MOUTH PAIN	1
MUSCLE SHAKING	1
MUSCLE TREMOR	1
MUSCLE WEAKNESS NOS	1
MYOCLONIC JERK	1
NEPHROPATHY	1
NERVE DAMAGE NOS	1
NEUROLOGICAL SYMPTOMS NOS	1
NON-REGENERATIVE ANAEMIA	1
NT - (LUMINAL) ENTEROPATHY	1
NT - HAEMORRHAGIC ENTERITIS	1
NT - RENAL LYMPHOMA	1
OEDEMA NOS	1
OEDEMA OF THE EXTREMITIES	1
OESOPHAGITIS	1
OPISTHOTONUS	1
OPTIC NERVE DISORDER	1
ORAL HAEMORRHAGE	1
ORAL MASS	1

ORAL MUCOSAL BLISTERING	1
ORAL ULCERATION	1
OSTEOSARCOMA	1
OVERDOSE	1
PAIN NOS	1
PALPEBRAL DISORDER NOS	1
PANCREATIC ENZYMES HIGH, BLOOD	1
PANCYTOPENIA	1
PARALYSIS	1
PARESIS	1
PARTIAL BLINDNESS	1
PARTIAL SIGHT	1
PERINATAL MORTALITY	1
PERIORBITAL OEDEMA	1
PHARYNGEAL DISORDER	1
PHARYNGEAL OEDEMA	1
PIGMENTATION DISORDER	1
PINNAL ERYTHEMA	1
PLATELET DISORDER NOS	1
POLLAKIURIA	1
PR-COLON, LESION(S)	1
PREMATURE PARTURITION	1
PR-EYE(S)/LID(S), LESION(S)	1
PR-GI, LESION(S)	1
PR-HEART, LESION(S)	1
PR-INTEST, LESION(S)	1
PR-KIDNEY(S), LESION(S)	1
PR-MOUTH/LIP(S), LESION(S)	1
PR-NERVE(S), LESION(S)	1
PRODUCT PROBLEM	1

PROLONGED CAPILLARY REFILL TIME	1
PROSTATE HYPERTROPHY	1
PR-PHARYNX, LESION(S)	1
PR-SPLEEN, LESION(S)	1
PR-WHOLE BODY, LESION(S)	1
PULMONARY CONGESTION	1
PULMONARY HAEMORRHAGE	1
PYELONEPHRITIS	1
QUADRIPLEGIA	1
RECTAL BLEEDING	1
RECTAL HAEMORRHAGE	1
RENAL INSUFFICIENCY	1
RESPIRATORY TRACT INFECTION NOS	1
RETINAL DISORDER NOS	1
RUNT	1
SCALY CONDITION NOS	1
SHOCK	1
SKIN AND TISSUE INFECTION NOS	1
SKIN WARMTH	1
SLOW HEART RATE	1
SOMNOLENCE	1
SQUINTING	1
STEATITIS	1
STERNOABDOMINAL RECUMBENCY	1
STIFF GAIT	1
STRAINING TO DEFECATE	1
STRANGURIA	1
STUPOR	1
SUCKLING DISORDER NOS	1
SUSPECTED INFECTIOUS AGENT TRANSMISSION	1

SWALLOWING DIFFICULT	1
SWOLLEN EYE	1
SWOLLEN FACE	1
SWOLLEN JOINT	1
SWOLLEN LIMB	1
SWOLLEN LIP	1
SYSTEMIC DISORDER NOS	1
TENSE ABDOMEN	1
THIRD EYELID PROLAPSE	1
THYROID GLAND DISORDER NOS	1
TONGUE DISORDER NOS	1
TRACHEAL AND LARYNGEAL DISORDER NOS	1
ULCERATION NOS	1
UNABLE TO JUMP	1
UNCLASSIFIABLE ADVERSE EVENT	1
UNCONSCIOUS	1
UNCONTROLLED DIABETES	1
UNDERDOSE	1
UNEQUAL PUPILS	1
UNPALATABLE	1
UNUSUAL STOOL COLOUR	1
URINARY TENESMUS	1
URTICARIAL RASH	1
UTERINE DISORDER NOS	1
UVEITIS	1
VASCULITIS	1
VOICE ALTERATION	1
WBC, URINE	1

Species: Human
Route of Administration: ORAL

Sign :	Number of Times Reported :
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ACCIDENTAL EXPOSURE	1
NASAL BLEEDING	1
VOMITING	1

Species: Human
Route of Administration: TOPICAL

Sign :	Number of Times Reported :
FEELING ANXIOUS	1
HEADACHE	1
HIVES	1
HYPERAESTHESIA	1
LOCALISED RASH	1
NAUSEA	1
SWOLLEN LIP	1
TINGLING SKIN	1
URTICARIAL RASH	1

Species: Human
Route of Administration: UNKNOWN

Sign :	Number of Times Reported :
EYE DISORDER NOS	1
ITCHING	1
LOCALISED NUMBNESS	1
THROAT IRRITATION	1
TINGLING SENSATION	1
TINGLING SKIN	1

Species: Wolf
Route of Administration: ORAL

Sign :	Number of Times Reported :
INEFFECTIVE, FLEAS	1
PRURITUS	1