

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: AFOXOLANER

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

Sign :	Number of Times Reported :
TIREDDNESS	1

Species: **Cat**  
Route of Administration: **UNKNOWN**

Sign :	Number of Times Reported :
HYPERACTIVITY	1
ITCHING	1
LETHARGY	1
VOCALISATION	1
VOMITING	1

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

Sign :	Number of Times Reported :
APATHY	1
BREATHLESSNESS	1
CRUST	1
FATIGUE	1
GENERALISED ITCHING	1
HIVES	1
LETHARGY	1
PINNAL REDDENING	1
PROSTRATION	1
REDDENING OF THE SKIN	1

RETCHING	1
SKIN ULCER	1
TIREDNESS	1
VOMITING	1

Species: Dog  
Route of Administration: ORAL

Sign :	Number of Times Reported :
VOMITING	870
LETHARGY	337
DIARRHOEA	332
PRURITUS	221
SEIZURE NOS	137
ANOREXIA	111
ITCHING	106
NOT EATING	97
PANTING	96
BEHAVIOURAL DISORDER NOS	84
ERYTHEMA	78
GENERALISED ITCHING	69
SCRATCHING	69
SHAKING	59
APPETITE LOSS	55
ABNORMAL TEST RESULT	52
FLAKING SKIN	51
RESTLESSNESS	51
BLOODY DIARRHOEA	49
DRY SKIN	48
INAPPETENCE	48
HIVES	47
LOOSE STOOL	44
REDDENING OF THE SKIN	42

ATAXIA	36
ANXIETY	35
DEATH	32
ELEVATED ALT	32
RASH	32
VOCALISATION	32
DECREASED APPETITE	31
HYPERSALIVATION	30
AGITATION	29
ELEVATED SAP	28
DROOLING	26
FEVER	26
HOT SPOT (PYOTRAUMATIC DERMATITIS)	25
LEUCOCYTOSIS	25
PICA NOS	25
SELF TRAUMA	25
LATERAL RECUMBENCY	24
POLYDIPSIA	24
FACIAL SWELLING	21
WEIGHT LOSS	21
DISORIENTATION	20
EMESIS	20
APATHY	19
ELEVATED BUN	19
HYPERACTIVITY	19
LICKING	19
ALOPECIA NOS	18
INAPPROPRIATE URINATION	18
SKIN DISORDERS NOS	18
SKIN LESION NOS	18

TWITCHING	18
ADIPSIA	17
HAIR LOSS NOS	17
MUSCULOSKELETAL DISORDER NOS	17
PAIN NOS	17
DEPRESSION	16
NEUTROPHILIA	16
TREMOR	16
DEHYDRATION	15
NOT DRINKING	15
PACING	15
SKIN SCAB	15
COUGH	14
FALLING	14
LOCALISED ITCHING	14
ABDOMINAL PAIN	13
ABNORMAL RADIOGRAPH FINDING	13
TACHYCARDIA	13
ALLERGIC REACTION	12
DEATH BY EUTHANASIA	12
ELEVATED CREATININE	12
GAGGING	12
HYPERTHERMIA	12
PADDLING	12
PAPULE	12
STIFFNESS NOS	12
BLOOD IN FAECES	11
COLLAPSE	11
DIGESTIVE TRACT DISORDER NOS	11
DYSPNOEA	11

ELEVATED LIPASE	11
MALODOUR	11
NAUSEA	11
PANCREATITIS	11
POLYURIA	11
PUSTULES	11
STAGGERING	11
TREMBLING	11
URINARY INCONTINENCE	11
WALKING DIFFICULTY	11
COLLAPSE NOS	10
CRUST	10
DRINKING A LOT	10
ELEVATED LIVER ENZYMES	10
ELEVATED TOTAL BILIRUBIN	10
HAIR SHEDDING	10
HYPERGLYCAEMIA	10
LOCALISED HAIR LOSS	10
AGGRESSION	9
ALOPECIA	9
CHEWING	9
ELEVATED AMYLASE	9
HEAD SHAKE - EAR DISORDER	9
INAPPROPRIATE DEFECATION	9
LACK OF EFFICACY	9
OCULAR DISCHARGE	9
PALE MUCOUS MEMBRANE	9
THROMBOCYTOPENIA	9
UNABLE TO STAND	9
ANAEMIA NOS	8

ELEVATED TEMPERATURE	8
FOAMING AT THE MOUTH	8
HAEMATURIA	8
LEUCOPENIA	8
MELAENA	8
MUCOUS STOOL	8
RELUCTANT TO MOVE	8
RETCHING	8
SKIN SORE	8
ALLERGIC PRURITUS	7
BLOOD IN VOMIT	7
CIRCLING	7
DERMATITIS	7
DRY MUCOUS MEMBRANE	7
FACIAL OEDEMA	7
GENERAL ILLNESS	7
GLAZED EYE	7
HIDING	7
HIND LIMB ATAXIA	7
HYPOGLYCAEMIA	7
INVOLUNTARY DEFECATION	7
MYOCLONIC JERK	7
PROSTRATION	7
REDUCED RESPONSES	7
SKIN INFLAMMATION NOS	7
STIFFNESS LIMB	7
WEAKNESS OF LIMB	7
ABNORMAL BREATHING	6
BACTERIAL SKIN INFECTION NOS	6
BALANCE IMPAIRED	6



EMESIS (MULTIPLE)	6
HEAD TILT	6
HEAD TREMOR	6
HYPOKALEMIC CONDITION	6
HYPOPROTEINAEMIA	6
LIVER DISORDER NOS	6
LUMP	6
LYMPHOPENIA	6
MYDRIASIS	6
RECUMBENCY	6
SLEEPINESS	6
STAR-GAZING	6
UNRESPONSIVE TO STIMULI	6
URINATION	6
ABNORMAL ULTRASOUND FINDING	5
ARCHED BACK	5
CONVULSION	5
ELEVATED AST	5
ERYTHEMATOUS RASH	5
EYE DISORDER NOS	5
FLATULENCE	5
HAEMATEMESIS	5
HYPEREXCITATION	5
HYPERPHOSPHATAEMIA	5
HYPOALBUMINAEMIA	5
HYPOCALCAEMIC CONDITION	5
ITCHY SKIN	5
LIMB WEAKNESS	5
LOCALISED RASH	5
MALAISE	5

PINNAL ERYTHEMA	5
RENAL FAILURE	5
SHIVERING	5
TACHYPNOEA	5
THROMBOCYTOSIS	5
URTICARIA	5
CUTANEOUS OEDEMA	4
DECREASED URINE CONCENTRATION	4
DISTRESS	4
DRUNKEN GAIT	4
EXCESSIVE LICKING AND/OR GROOMING	4
GASTROENTERITIS	4
HAIR CHANGE	4
HYPOTHERMIA	4
ICTERUS	4
LISTLESS	4
LYMPHOCYTOSIS	4
MUSCULOSKELETAL PAIN	4
NEUROLOGICAL SIGNS NOS	4
NOT SLEEPING	4
PINNAE DISORDER	4
POLYPNOEA	4
RENAL DISORDER NOS	4
RIGIDITY	4
SCALE	4
SLEEP DISTURBANCE NOS	4
STUMBLING GAIT	4
SWELLING AROUND EYE	4
SWELLING NOS	4
TENSE ABDOMEN	4

UNCONSCIOUS	4
UNEXPLAINED DEATH	4
UNSTEADY GAIT	4
WELT	4
ABNORMAL POSTURE NOS	3
ABNORMAL RED BLOOD CELL	3
ADDISON'S DISEASE	3
ALLERGIC DERMATITIS	3
ANAPHYLACTIC-TYPE REACTION	3
BALANCE PROBLEM	3
BANDS(NEUTROPHILS) HIGH, BLOOD	3
BILIRUBINURIA	3
BLISTERING	3
CLOSED EYELID	3
COLLAPSE OF LEG	3
CONFUSED	3
CONFUSION	3
CONGESTION OF MUCOUS MEMBRANE	3
DIABETES MELLITUS	3
EAR IRRITATION	3
ELEVATED GAMMA-GLUTAMYL TRANSFERASE (GGT)	3
EOSINOPENIA	3
EPIDERMAL COLLARETTE	3
EYE REDNESS	3
FOAM IN THE MOUTH	3
FREQUENT URINATION	3
FUNGAL SKIN INFECTION NOS	3
FURUNCULOSIS	3
GUT SOUNDS INCREASED	3
HAEMATOCHEDIA	3

HAEMORRHAGIC DIARRHOEA	3
HEAD SHAKE	3
HYPERAESTHESIA	3
HYPERMETRIA	3
HYPOPHOSPHATAEMIA	3
IMMUNE MEDIATED HAEMOLYTIC ANAEMIA	3
INCOORDINATION	3
INCREASED BORBORYGMUS	3
INCREASED HEART RATE	3
IRREGULAR BREATHING	3
LAMENESS	3
LOCALISED PAIN NOS	3
LOSS OF BOWEL CONTROL	3
LOSS OF VOLUNTARY MOVEMENT	3
MONOCYTOSIS	3
MUSCLE SPASM NOS	3
NASAL DISCHARGE	3
NEUTROPENIA	3
NYSTAGMUS	3
OFF COLOUR	3
OPISTHOTONUS	3
OTITIS EXTERNA	3
PINNAL OEDEMA	3
PINNAL REDDENING	3
POLLAKIURIA	3
PROTEINURIA	3
PYODERMA	3
PYREXIA	3
RED EYE	3
SEBORRHOEA	3

SKIN IRRITATION	3
SNEEZING	3
STOMACH UPSET	3
SWOLLEN EYE	3
SWOLLEN LIP	3
SWOLLEN LYMPH NODE	3
TENESMUS	3
TIREDNESS	3
TREMOR OF LIMB	3
UNABLE TO RISE	3
VESTIBULAR DISORDER NOS	3
WEAKNESS	3
WHEEZING	3
ABDOMINAL CAVITY DISORDER NOS	2
ABN COLOR, URINE	2
ABNORMAL MOVEMENT NOS	2
ABNORMAL NECROPSY FINDING	2
ABNORMAL PUPIL LIGHT REFLEX	2
ALOPECIA LOCAL	2
ANAL IRRITATION	2
ARTHRITIS	2
ASCITES	2
BARKING	2
BITING	2
BLOOD LOSS NOS	2
BOIL	2
BREATHING DIFFICULTY	2
COLITIS	2
COMA	2
CONJUNCTIVAL OEDEMA	2

CONSTIPATION	2
CRYING	2
CYANOSIS	2
DECREASED PACKED CELL VOLUME (PCV)	2
DERMAL THICKENING	2
DISORIENTED STATE	2
DROOPING EYELID	2
DULLNESS	2
EAR FLAP OEDEMA	2
EAR INFECTION NOS	2
ELECTROLYTE DISORDER	2
ENLARGED LIVER	2
ENTERITIS	2
EPILEPTIC SEIZURE	2
EPISTAXIS	2
EXCESSIVE THIRST	2
EXERCISE INTOLERANCE	2
EYE INFLAMMATION NOS	2
EYELID OEDEMA	2
EYES ROLLING BACK	2
FACE AND NECK SWELLING	2
FIT	2
HAEMOCONCENTRATION	2
HEAD BOBBING	2
HEART MURMUR	2
HEPATOMEGALY	2
HEPATOPATHY	2
HIND LIMB PARESIS	2
HYDROCEPHALUS	2
HYPERPIGMENTATION	2

HYPERVENTILATION	2
HYPOTENSION	2
IMPAIRED CONSCIOUSNESS	2
INCREASED RESPIRATORY RATE	2
JAUNDICE	2
JOINT PAIN	2
JOINT STIFFNESS	2
LABOURED BREATHING	2
LIMPING	2
LIP LICKING	2
LIP OEDEMA	2
LOCAL SWELLING (NOT APPLICATION SITE)	2
LOSS OF CONDITION	2
MUSCLE TREMOR	2
OEDEMA OF THE EXTREMITIES	2
PAPULAR RASH	2
PARALYSIS NOS	2
PERIORBITAL OEDEMA	2
PIGMENTATION DISORDER	2
PLATELETS HIGH, BLOOD	2
PROPRIOCEPTION LOSS	2
PURULENT LESION(S)	2
RECTAL BLEEDING	2
REGURGITATION	2
SICKNESS	2
SKIN SWELLING	2
SKIN ULCER	2
STOMACH PAIN	2
STRIDOR (UPPER RESPIRATORY; FOR LOWER RESPIRATORY SEE ALSO BRONCHIAL RALE)	2
SUDDEN DEATH	2

TARRY OR BLACK STOOL	2
TENSE MUSCLES	2
ULCERATION NOS	2
UNCOMFORTABLE	2
URINE ABNORMALITIES NOS	2
VAGINAL DISCHARGE	2
WOBBLER	2
ABDOMINAL CAVITY HAEMORRHAGE	1
ABDOMINAL DISCOMFORT	1
ABDOMINAL OEDEMA	1
ABNORMAL MENACE REFLEX TEST	1
ABNORMAL STOOL COLOURATION	1
ABORTION	1
ACTING TENSE	1
ALBUMIN/GLOBULIN RATIO HI, BLD	1
ALKALINE URINE	1
ALLERGY NOS	1
ANAL OEDEMA	1
ANGIOEDEMA	1
APNOEA	1
APPLICATION SITE ERYTHEMA	1
ARRHYTHMIA	1
BLADDER INCONTINENCE	1
BLINDNESS	1
BLOATED	1
BLOOD AND LYMPHATIC SYSTEM DISORDER NOS	1
BLOODSHOT EYE	1
BONE AND JOINT DISORDER NOS	1
BONE MARROW DISORDER NOS	1
BRADYCARDIA	1



BRONCHITIS	1
BRONCHOPULMONARY INFLAMMATION	1
BRUISING	1
CELLULITIS	1
CHATTERING OF TEETH	1
CHEMOSIS	1
CHLORIDE LOW, BLOOD	1
CHOLESTEROL LOW, BLOOD	1
CIRCULATORY COLLAPSE	1
CIRCULATORY DISORDER NOS	1
CIRCULATORY SHOCK	1
CLAW / HOOF / NAIL LOSS	1
COGNITIVE DISTURBANCE	1
CONGENITAL MUSCULO-SKELETAL DISORDER	1
CONJUNCTIVAL IRRITATION	1
CONJUNCTIVITIS	1
CONSTRICTED PUPILS	1
COUGHING UP BLOOD	1
CREATININE HIGH, BLOOD	1
DECREASED ACTIVITY	1
DECREASED BOWEL MOVEMENTS	1
DECREASED CHOLESTEROL (TOTAL)	1
DENTAL DISEASE	1
DEPENDENT OEDEMA	1
DIABETES	1
DIABETIC KETOACIDOSIS	1
DIABETIC KETONURIA	1
DIGESTIVE TRACT NEOPLASM NOS	1
DIGESTIVE TRACT STENOSIS AND OBSTRUCTION NOS	1
DISCOLOURED URINE	1

DISTENSION OF ABDOMEN	1
DRY COAT	1
DULL	1
EAR DISCHARGE	1
EAR FLAPPING/TWITCHING	1
ECZEMA	1
ELEVATED CREATININE-KINASE (CK)	1
ELEVATED RENAL PARAMETERS	1
EMPROSTHOTONUS	1
ENLARGED KIDNEY(S)	1
ENVIRONMENTAL ADVERSE EVENT	1
EOSINOPHILIA	1
EPIPHORA	1
EXCITATION	1
EXTERNAL EAR DISORDER NOS	1
EYE ITCHING	1
EYE PARALYSIS	1
FACIAL PALSY	1
FACIAL PARALYSIS	1
FACIAL RASH	1
FAECAL INCONTINENCE	1
FATIGUE	1
FEBRILE	1
FLUID IN ABDOMEN NOS	1
FOLLICULITIS	1
FRACTURE	1
GAIT ABNORMALITY	1
GALL BLADDER & BILE DUCT DISORDER NOS	1
GASTRIC DISTENSION	1
GASTRITIS	1

GENERALISED INFLAMMATION OF EYE	1
GENERALISED RED SPOT	1
GENERALISED WEAKNESS	1
GINGIVAL DISORDER	1
GLUCOSURIA	1
GREASY SKIN	1
GUM DISORDER NOS	1
GUT PAIN	1
HAEMATOMA NOS	1
HAEMOLYTIC ANAEMIA	1
HAEMORRHAGE NOS	1
HAEMORRHAGIC GASTROENTERITIS	1
HAIR COAT DISCOLOURATION	1
HAIR MODIFICATION NOS	1
HAIR STANDING ON END	1
HALITOSIS	1
HALLUCINATION	1
HEART FAILURE	1
HEART POUNDING	1
HEMATOCRIT(HCT) HIGH, BLOOD	1
HEMOCONCENTRATION	1
HEPATIC DISORDER NOS	1
HEPATIC NEOPLASM	1
HIND LIMB PARALYSIS	1
HORIZONTAL NYSTAGMUS	1
HYPERCALCAEMIA	1
HYPEREXTENSION	1
HYPERKALEMIC CONDITION	1
HYPERPROTEINAEMIA	1
HYPERTENSION	1

HYPONATREMIA	1
HYPOPARATHYROIDISM	1
ILEUS	1
IMMUNE MEDIATED THROMBOCYTOPENIA	1
IMPAIRED VISION	1
IMPAIRED VOCALISATION	1
IMPLANT SITE PRURITUS	1
INCORRECT DOSE ADMINISTERED	1
INCREASED SALIVATION	1
INCREASED SENSITIVITY TO SOUND	1
INCREASED SKIN SENSITIVITY	1
INDIGESTION	1
INEFFECTIVE, FLEAS	1
INJECTION SITE PAIN	1
INVOLUNTARY MOVEMENT	1
IRRITABILITY	1
ISOSTHENURIA	1
ITCHY RASH	1
LACRIMATION INCREASED	1
LICHENIFICATION	1
LIVER FAILURE	1
LOCALISED OEDEMA (NOT APPLICATION SITE)	1
LUNG OEDEMA	1
MAMMARY GLAND NEOPLASM NOS	1
MENTAL CONFUSION	1
MOIST DERMATITIS	1
MOUTH IRRITATION	1
MOUTH PAIN	1
MUCOCUTANEOUS ULCER	1
MUCOSA PETECHIAE	1

MUSCLE DEGENERATION	1
MUSCLE SHAKING	1
MUSCLE WASTING	1
MUSCLE WEAKNESS NOS	1
MUSCULAR HYPERTONICITY	1
NAIL DISORDERS NOS	1
NASAL CONGESTION	1
NEOPLASIA NOS	1
NEPHROPATHY	1
NERVOUS SYSTEM DISORDER NOS	1
NEUROLOGICAL SYMPTOMS NOS	1
NON-REGENERATIVE ANAEMIA	1
OEDEMA NOS	1
ORAL BLEEDING	1
ORAL CAVITY DISORDER NOS	1
ORAL ULCERATION	1
OTHER BLOOD DISORDER NOS	1
OTITIS NOS	1
PALPITATION	1
PARESIS	1
PEELING SKIN	1
PEMPHIGUS FOLIACEUS	1
PERIODONTAL DISORDER	1
PETECHIAE NOS	1
PIMPLES	1
PINNAL HAEMORRHAGE	1
PLEURAL EFFUSION	1
PNEUMONIA	1
PODODERMATITIS	1
POLYCYTHEMIA	1

PREMATURE PARTURITION	1
PR-GI, LESION(S)	1
PR-MULTIPLE SITES, BLOOD	1
PROLONGED CAPILLARY REFILL TIME	1
PRURITIC RASH	1
PTYALISM	1
PULMONARY CONGESTION	1
PULMONARY OEDEMA	1
PYOMETRA	1
RED BLOOD CELL DISORDER	1
REDUCED LEVEL OF CONSCIOUSNESS	1
REDUCED REFLEXES	1
RENAL INSUFFICIENCY	1
RESPIRATORY DISTRESS	1
RESPIRATORY SIGNS	1
RETICULOCYTOSIS	1
RUBBING	1
SCLERITIS	1
SCOOTING	1
SEDATION	1
SELF MUTILATION	1
SGOT HIGH	1
SHALLOW BREATHING	1
SHOCK	1
SKELETAL MUSCLE PARALYSIS	1
SKIN AND TISSUE INFECTION NOS	1
SKIN HYPERAEMIA	1
SKIN SLOUGH	1
SMALL LIVER	1
SMELL ALTERATION	1

SORE LIP	1
SPLEEN AND RETICULO-ENDOTHELIAL SYSTEM DISORDER NOS	1
SPLENOMEGALY	1
SPONDYLOPATHY	1
SPONDYLOSIS	1
STERILE	1
STERNOABDOMINAL RECUMBENCY	1
STRANGURIA	1
STROKE	1
STUPOR	1
SWALLOWING DIFFICULT	1
SWOLLEN FEET	1
SYSTEMIC DISORDER NOS	1
TETANY	1
THIRD EYELID PROTRUSION	1
THROAT IRRITATION	1
TONGUE DISORDER NOS	1
TONGUE PROTRUSION	1
TONIC SEIZURE	1
TONIC-CLONIC SEIZURE	1
TRACHEAL OBSTRUCTION	1
UNCONTROLLED MICTURITION	1
URAEMIA	1
URINARY BLADDER DISORDER NOS	1
URINARY RETENTION	1
URINARY TRACT DISORDER NOS	1
URINARY TRACT INFECTION	1
URINARY TRACT NEOPLASM	1
UROLITHIASIS	1
URTICARIAL ERYTHEMA	1

URTICARIAL RASH	1
VAGINAL HAEMORRHAGE	1
VASCULITIS	1
VULVAR OEDEMA	1
VULVITIS	1
WBC, URINE	1

Species: Dog  
Route of Administration: OTHER

Sign :	Number of Times Reported :
VOMITING	3
DIARRHOEA	1
DRY SKIN	1
LETHARGY	1
PEELING SKIN	1

Species: Dog  
Route of Administration: RECTAL

Sign :	Number of Times Reported :
VOMITING	1

Species: Dog  
Route of Administration: UNKNOWN

Sign :	Number of Times Reported :
VOMITING	47
LETHARGY	10
PRURITUS	10
SEIZURE NOS	9
BEHAVIOURAL DISORDER NOS	8
GENERALISED ITCHING	6
DIARRHOEA	5
ERYTHEMA	5
HIVES	5
ITCHING	5
SKIN DISORDERS NOS	5



HAIR LOSS NOS	4
NOT EATING	4
SCRATCHING	4
ANOREXIA	3
DEATH	3
DRY SKIN	3
HYPERACTIVITY	3
RASH	3
VOCALISATION	3
AGITATION	2
ALLERGIC REACTION	2
AUTOIMMUNE DISORDER NOS	2
BARKING	2
DEATH BY EUTHANASIA	2
DROOLING	2
IMPAIRED CONSCIOUSNESS	2
INCOORDINATION	2
INEFFECTIVE, FLEAS	2
LABOURED BREATHING	2
LOOSE STOOL	2
MELAENA	2
NEUROLOGICAL SIGNS NOS	2
SELF TRAUMA	2
SHAKING	2
SKIN IRRITATION	2
WHEAL	2
AGGRESSION	1
ALLERGIC PRURITUS	1
ALLERGY NOS	1
ALOPECIA	1

ALOPECIA NOS	1
ANAPHYLACTIC-TYPE REACTION	1
ANXIETY	1
APPETITE LOSS	1
BLOODY DIARRHOEA	1
BRADYCARDIA	1
CONGENITAL DISORDER NOS	1
COUGH	1
DEHYDRATION	1
DERMATITIS	1
DIGESTIVE TRACT DISORDER NOS	1
DISORIENTATION	1
DISTENSION OF ABDOMEN	1
DISTRESS	1
DRUG DOSE ADMINISTRATION INTERVAL TOO SHORT	1
ERYTHEMATOUS RASH	1
FLAKING SKIN	1
GASTRIC DISTENSION	1
HAEMATOCHEDIA	1
HAEMORRHAGIC DIARRHOEA	1
HAIR CHANGE	1
HEART FAILURE	1
HYPEREXCITATION	1
HYPERSALIVATION	1
HYPERTHERMIA	1
INCREASED RESPIRATORY RATE	1
ITCHY SKIN	1
LACK OF EFFICACY	1
LICKING	1
LIP OEDEMA	1

LUNG SOUND	1
MUSCLE DEGENERATION	1
MUSCULOSKELETAL DISORDER NOS	1
MYDRIASIS	1
NAUSEA	1
NOT DRINKING	1
PALPABLE MASS NOS	1
PANCREAS DISORDER	1
PANTING	1
PICA NOS	1
PINNAE DISORDER	1
POLYPNOEA	1
POLYURIA	1
PULMONARY OEDEMA	1
PURULENT LESION(S)	1
PYODERMA	1
REDDENING OF THE SKIN	1
RENAL DISORDER NOS	1
SKIN LESION NOS	1
SKIN SCAB	1
STAGGERING	1
STROKE	1
SWOLLEN EYE	1
TACHYCARDIA	1
TREMBLING	1
UNABLE TO STAND	1
UNRESPONSIVE TO STIMULI	1
URINARY INCONTINENCE	1
WALKING DIFFICULTY	1
WEIGHT LOSS	1

WHEEZING	1
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Species: Fox  
Route of Administration: ORAL

Sign :	Number of Times Reported :
BEHAVIOURAL DISORDER NOS	1
HYPERACTIVITY	1
RESTLESSNESS	1

Species: Horse  
Route of Administration: ORAL

Sign :	Number of Times Reported :
NOT DRINKING	1
NOT EATING	1
VOMITING	1

Species: Human  
Route of Administration: OTHER

Sign :	Number of Times Reported :
HYPERTENSION	1
RASH	1

Species: Human  
Route of Administration: UNKNOWN

Sign :	Number of Times Reported :
EYELID OEDEMA	1
HIVES	1
ITCHING	1