

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

A search of CVM's Adverse Drug Event (ADE) database was performed on 5/18/2017. The search parameters were:

<u>Active ingredient(s):</u>	afoxolaner, fluralaner and sarolaner
<u>Reports received:</u>	From 1/28/2017 through 5/2/2017
<u>Case type:</u>	Spontaneous ADE report
<u>Species:</u>	All
<u>Route of administration:</u>	All

For each drug (active ingredient), 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.

May 18, 2017

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 sarolaner are approved for oral use in **dogs** only. Fluralaner is approved for both oral and topical use in **dogs** only. For the time period of the ADE database search (1/28/2017 - 5/2/2017), there were a total of 720 ADE reports received for afoxolaner for dogs, a total of 1681 ADE reports received for fluralaner for dogs, and a total of 98 ADE reports received for sarolaner for dogs.

The following table shows the number of reports broken down by all species for which reports have been received during this time period:

Species	# Afoxolaner reports	# Fluralaner reports	# Sarolaner reports
Dog	720	1681	98
Cat	1	196	4
Human (accidental exposures)	4	29	0
Other Birds		1	
Total # ADE reports, all species	725	1907	102

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

May 18, 2017

actually 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 : 28-Jan-2017 -thru- 02-May-2017
Included 1932a cases = : True
Included Medicated Feed cases = : False

DRUG: FLURALANER

Species: Cat
 Route of Administration: ORAL

Sign :	Number of Times Reported :
HYPERSALIVATION	3
ABNORMAL RADIOGRAPH FINDING	1
DILATED PUPILS	1
DROOLING	1
DRUG ADMINISTRATION ERROR	1
PRODUCT PROBLEM	1
VOMITING	1
WHEEZING	1

Species: Cat
 Route of Administration: TOPICAL

Sign :	Number of Times Reported :
APPLICATION SITE HAIR LOSS	28
APPLICATION SITE ALOPECIA	22
LETHARGY	21
APPLICATION SITE GREASY FUR	16
EMESIS (MULTIPLE)	15
HYPERSALIVATION	11
APPLICATION SITE REDDENING	9
DROOLING	9
DECREASED APPETITE	7
PRURITUS	7

DRUG: FLURALANERSpecies: Cat
Route of Administration: TOPICAL

Sign :	Number of Times Reported :
DIARRHOEA	6
VOMITING	6
ANOREXIA	5
APPLICATION SITE SCRATCHING	5
FOAMING AT THE MOUTH	5
HIDING	5
INEFFECTIVE, FLEAS	5
AGITATION	4
APPLICATION SITE ERYTHEMA	4
APPLICATION SITE SCAB	4
ATAXIA	4
BEHAVIOURAL DISORDER NOS	4
ELEVATED CREATININE	4
LICKING AT APPLICATION SITE	4
ALOPECIA	3
APPLICATION SITE HAIR CHANGE	3
DEATH	3
SEIZURE NOS	3
TWITCHING	3
ABNORMAL TEST RESULT	2
ANISOCORIA	2
APPLICATION SITE BURN	2
APPLICATION SITE HOT SPOT	2
APPLICATION SITE LESION	2
APPLICATION SITE PRURITUS	2
ELEVATED BUN	2

DRUG: FLURALANER

Species: Cat
Route of Administration: TOPICAL

Sign :	Number of Times Reported :
EXCESSIVE LICKING AND/OR GROOMING	2
FEVER	2
HYPERACTIVITY	2
HYPERGLYCAEMIA	2
HYPOPHOSPHATAEMIA	2
ITCHING	2
LOCALISED HAIR LOSS	2
MENTAL FUNCTION DECREASED	2
SCRATCHING	2
SLEEPINESS - SYSTEMIC DISORDER	2
THROMBOCYTOSIS	2
VOCALISATION	2
WEIGHT LOSS	2
ABDOMINAL EFFUSION	1
ABNORMAL MOVEMENT NOS	1
ABNORMAL NECROPSY FINDING	1
ABNORMAL POSTURE NOS	1
ABRASION	1
ADIPSIA	1
ALOPECIA LOCAL	1
ANAEMIA NOS	1
APPLICATION SITE BLISTER	1
APPLICATION SITE CRUST	1
APPLICATION SITE DERMATITIS	1
APPLICATION SITE DRY SKIN	1
APPLICATION SITE ITCHING	1

DRUG: FLURALANERSpecies: Cat
Route of Administration: TOPICAL

Sign :	Number of Times Reported :
APPLICATION SITE MUCOPURULENT DISCHARGE	1
APPLICATION SITE PAIN	1
APPLICATION SITE PAPULE	1
APPLICATION SITE RASH	1
APPLICATION SITE REACTION NOS	1
APPLICATION SITE SELF TRAUMA	1
APPLICATION SITE SKIN SCALING	1
APPLICATION SITE ULCER	1
BITING	1
CIRCULATORY COLLAPSE	1
CLUMSY	1
COLLAPSE	1
COLLAPSE NOS	1
DEATH BY EUTHANASIA	1
DECREASED ACTIVITY	1
DECREASED PACKED CELL VOLUME (PCV)	1
DECREASED RED BLOOD CELL COUNT	1
DILATED PUPILS	1
DILATED RENAL PELVIS	1
ELEVATED ALT	1
ELEVATED AMYLASE	1
ELEVATED AST	1
ELEVATED TOTAL BILIRUBIN	1
ERYTHEMA	1
FOAM IN THE MOUTH	1
GAIT ABNORMALITY	1

DRUG: FLURALANERSpecies: Cat
Route of Administration: TOPICAL

Sign :	Number of Times Reported :
GENERAL HAIR LOSS	1
HAIR STANDING ON END	1
HEAD SHAKE - BEHAVIOURAL DISORDER	1
HEPATIC DISORDER NOS	1
HIND LIMB ATAXIA	1
HIND LIMB PARESIS	1
HYPERAESTHESIA	1
HYPERPHOSPHATAEMIA	1
HYPOKALEAEMIA	1
HYPOTHERMIA	1
INAPPETENCE	1
INCREASED PERCENTAGE RETICULOCYTES	1
INEFFECTIVE, TICKS	1
INTESTINAL DISORDER NOS	1
LABOURED BREATHING	1
LACK OF EFFICACY	1
LEUCOCYTOSIS	1
LICKING	1
LOW PLATELET COUNT	1
LUNG COLLAPSE	1
LYMPHOCYTOSIS	1
MALaise	1
MUSCLE TREMOR	1
MYDRIASIS	1
NEUROMUSCULAR DISORDER NOS	1
NOT DRINKING	1

DRUG: FLURALANERSpecies: Cat
Route of Administration: TOPICAL

Sign :	Number of Times Reported :
NOT EATING	1
NT - RENAL CYSTS HYDRONEPHROSIS	1
ORAL ULCERATION	1
OTHER EAR DISORDER NOS	1
PLEURAL EFFUSION	1
PROFUSE BLEEDING	1
PULMONARY CONGESTION	1
PULMONARY DISORDER NOS	1
PULMONARY HAEMORRHAGE	1
PULMONARY OEDEMA	1
RELUCTANT TO MOVE	1
RENAL DISORDER NOS	1
SHAKING	1
SKIN SCAB	1
SKIN SLOUGH	1
SKIN ULCER	1
SLEEP DISTURBANCE NOS	1
SQUINTING	1
SUDDEN DEATH	1
T4 HIGH, SERUM	1
TACHYCARDIA	1
THROMBOCYTOPENIA	1
TIREDNESS	1
ULCERATION NOS	1
URETERIC DISORDER	1

DRUG: FLURALANER

Species: Cat
Route of Administration: UNKNOWN

Sign :	Number of Times Reported :
PRURITUS	1

Species: Dog
Route of Administration: ORAL

Sign :	Number of Times Reported :
VOMITING	585
EMESIS (MULTIPLE)	150
LETHARGY	135
DIARRHOEA	103
LACK OF EFFICACY (ECTOPARASITES)	90
SEIZURE NOS	63
DECREASED APPETITE	41
BEHAVIOURAL DISORDER NOS	27
DEATH	27
INAPPETENCE	27
ANOREXIA	26
ABNORMAL TEST RESULT	24
PRURITUS	24
DEATH BY EUTHANASIA	21
ATAXIA	18
HIVES	17
FEVER	16
ELEVATED ALT	15
ITCHING	15
POLYDIPSIA	15
BLOODY DIARRHOEA	14
INAPPROPRIATE URINATION	14

DRUG: FLURALANERSpecies: Dog
Route of Administration: ORAL

Sign :	Number of Times Reported :
LOOSE STOOL	14
NOT EATING	14
PANTING	14
SHAKING	14
VOCALISATION	14
ABNORMAL RADIOGRAPH FINDING	12
SCRATCHING	12
DROOLING	11
ELEVATED CREATININE	11
ELEVATED SAP	11
WEIGHT LOSS	11
ELEVATED BUN	10
TREMOR	10
WEAKNESS	10
DECREASED DRINKING	9
DEHYDRATION	9
LEUCOCYTOSIS	9
POLYURIA	9
ABNORMAL ULTRASOUND FINDING	8
DECREASED PACKED CELL VOLUME (PCV)	8
EMESIS	8
FACIAL SWELLING	8
LACK OF EFFICACY	8
URINARY INCONTINENCE	8
ANXIETY	7
COUGH	7

DRUG: FLURALANERSpecies: Dog
Route of Administration: ORAL

Sign :	Number of Times Reported :
HYPERPHOSPHATAEMIA	7
LAMENESS	7
NAUSEA	7
SKIN LESION NOS	7
TREMBLING	7
ABNORMAL NECROPSY FINDING	6
AGGRESSION	6
ANAEMIA NOS	6
DECREASED ACTIVITY	6
DRINKING A LOT	6
ELEVATED CHOLESTEROL (TOTAL)	6
HIDING	6
MEDICATION ERROR	6
NEUTROPHILIA	6
NOT DRINKING	6
PANCREATITIS	6
PICA NOS	6
PROPRIOCEPTION DEFICIT	6
RESTLESSNESS	6
WALKING DIFFICULTY	6
BLOOD IN VOMIT	5
ELEVATED AMYLASE	5
ELEVATED LIPASE	5
ELEVATED LIVER ENZYMES	5
ELEVATED TOTAL BILIRUBIN	5
FALLING	5

DRUG: FLURALANER

Species: Dog
Route of Administration: ORAL

Sign :	Number of Times Reported :
GAGGING	5
GENERALISED RASH	5
HYPERACTIVITY	5
HYPOGLYCAEMIA	5
LIMB WEAKNESS	5
TACHYCARDIA	5
UNABLE TO STAND	5
ABDOMINAL PAIN	4
ADIPSIA	4
AGITATION	4
ALOPECIA LOCAL	4
BILIRUBINURIA	4
BLOOD IN FAECES	4
BLOOD IN URINE	4
DISORIENTATION	4
ELEVATED AST	4
GENERALISED ITCHING	4
HAIR SHEDDING	4
HEAD TREMOR	4
HYPERGLYCAEMIA	4
HYPERSALIVATION	4
INCREASED PACKED CELL VOLUME (PCV)	4
LYMPHOPENIA	4
MALaise	4
RENAL FAILURE	4
TIREDNESS	4

DRUG: FLURALANERSpecies: Dog
Route of Administration: ORAL

Sign :	Number of Times Reported :
ABNORMAL CYTOLOGY	3
ABNORMAL STOOL COLOURATION	3
APPETITE LOSS	3
BREATHING DIFFICULTY	3
CONGENITAL DISORDER NOS	3
CONJUNCTIVITIS	3
CRUST	3
DECREASED URINE CONCENTRATION	3
DERMATITIS	3
DIGESTIVE TRACT DISORDER NOS	3
DISORDER OF GASTROINTESTINAL FLORA	3
DISORIENTED STATE	3
DISTENSION OF ABDOMEN	3
ENLARGED LIVER	3
ERYTHEMA	3
ERYTHEMATOUS RASH	3
EXCESSIVE THIRST	3
FACIAL OEDEMA	3
FLATULENCE	3
FREQUENT URINATION	3
GAIT ABNORMALITY	3
GALL BLADDER & BILE DUCT DISORDER NOS	3
GASTROENTERITIS	3
GENERAL PAIN	3
HEPATOMEGALY	3
HYPERALBUMINAEMIA	3

DRUG: FLURALANERSpecies: Dog
Route of Administration: ORAL

Sign :	Number of Times Reported :
HYPERCALCAEMIA	3
HYPERPROTEINAEMIA	3
HYPOALBUMINAEMIA	3
HYPOKALEAEMIA	3
IMMUNE MEDIATED HAEMOLYTIC ANAEMIA	3
INAPPROPRIATE DEFECATION	3
LIP LICKING	3
MALODOUR	3
MONOCYTOSIS	3
MUCOUS STOOL	3
MUSCULOSKELETAL DISORDER NOS	3
NYSTAGMUS	3
PACING	3
PR-LIVER, LESION(S)	3
PR-LUNG(S), EDEMA	3
PRODUCT PROBLEM	3
PULMONARY CONGESTION	3
PULMONARY OEDEMA	3
REDDENING OF THE SKIN	3
RELUCTANT TO MOVE	3
RETCHING	3
SKIN SCAB	3
SMELLY BREATH	3
STAR-GAZING	3
TARRY OR BLACK STOOL	3
THROMBOCYTOPENIA	3

DRUG: FLURALANER

Species: Dog
Route of Administration: ORAL

Sign :	Number of Times Reported :
URINARY TRACT INFECTION	3
ABDOMINAL DISCOMFORT	2
ABNORMAL MENACE REFLEX TEST	2
ABNORMAL RED BLOOD CELL	2
ALLERGIC REACTION	2
ALOPECIA	2
BACTERIAL SKIN INFECTION NOS	2
CATARACT	2
CHRONIC RENAL FAILURE	2
COLLAPSE NOS	2
CONSTIPATION	2
DECREASED RED BLOOD CELL COUNT	2
DEPRESSION	2
DISCOLOURED URINE	2
ELEVATED BILE ACIDS	2
ELEVATED GAMMA-GLUTAMYL TRANSFERASE (GGT)	2
ELEVATED GLOBULINS	2
ENLARGED LYMPH NODE(S)	2
EXCESSIVE SWEATING	2
EYE DISORDER NOS	2
FAECAL INCONTINENCE	2
FLAKING SKIN	2
GENERAL ILLNESS	2
GENERALISED WEAKNESS	2
GREASY SKIN	2
HAEMATEMESIS	2

DRUG: FLURALANERSpecies: Dog
Route of Administration: ORAL

Sign :	Number of Times Reported :
HAEMORRHAGE NOS	2
HEPATIC DISORDER NOS	2
HIND LIMB PARALYSIS	2
HYPERAESTHESIA	2
HYPERTHERMIA	2
HYPOTHERMIA	2
HYPOTHYROIDISM	2
ICTERUS	2
INCREASED SALIVATION	2
INTESTINAL DISORDER NOS	2
ISOSTHENURIA	2
ITCHY SKIN	2
JOINT SWELLING	2
LABOURED BREATHING	2
LEUCOPENIA	2
LIPOMA	2
LISTLESS	2
LIVER DISORDER NOS	2
LOCALISED HAIR LOSS	2
LOCALISED RASH	2
LUMBAR PAIN	2
LYMPHOMA	2
MUSCLE WASTING	2
MYDRIASIS	2
MYOCLONIC JERK	2
NASAL BLEEDING	2

DRUG: FLURALANERSpecies: Dog
Route of Administration: ORAL

Sign :	Number of Times Reported :
NEUROLOGICAL SIGNS NOS	2
NEUTROPENIA	2
NT - HEPATIC LIPIDOSIS (STEATOSIS)	2
OTITIS EXTERNA	2
PALE MUCOUS MEMBRANE	2
PANCREAS DISORDER	2
PAPULE	2
PARTIAL ANOREXIA	2
PINNAE DISORDER	2
PUSTULES	2
RASH	2
RECUMBENCY	2
REDUCED CONCEPTION RATE	2
REGURGITATION	2
RETINAL DEGENERATION	2
SKIN DISORDERS NOS	2
SPLEEN AND RETICULO-ENDOTHELIAL SYSTEM DISORDER NOS	2
SPLENOMEGALY	2
STAGGERING	2
STIFFNESS LIMB	2
STIFFNESS NOS	2
STILLBIRTH	2
STOMACH PAIN	2
STUMBLING GAIT	2
SWOLLEN EYE	2
TACHYPNOEA	2

DRUG: FLURALANERSpecies: Dog
Route of Administration: ORAL

Sign :	Number of Times Reported :
TWITCHING	2
UNCLASSIFIABLE ADVERSE EVENT	2
UNCOMFORTABLE	2
WHEEZING	2
ABDOMINAL EFFUSION	1
ABDOMINAL MASS	1
ABNORMAL BIRTH WEIGHT	1
ABNORMAL ECG	1
ABNORMAL PUPIL LIGHT REFLEX	1
ABNORMAL VISION	1
ACUTE RENAL FAILURE	1
ALLERGIC DERMATITIS	1
ALLERGY TO FOOD	1
ALOPECIA GENERAL	1
APPETITE DISORDER NOS	1
APPREHENSION	1
ARCHED BACK	1
ARRHYTHMIA	1
AURAL HAEMATOMA	1
AZOTAEMIA	1
BALANCE IMPAIRED	1
BALANCE PROBLEM	1
BANDS(NEUTROPHILS) HIGH, BLOOD	1
BARKING	1
BITING	1
BLINDNESS	1

DRUG: FLURALANERSpecies: Dog
Route of Administration: ORAL

Sign :	Number of Times Reported :
BLOATED STOMACH	1
BONE AND JOINT DISORDER NOS	1
BONE MARROW APLASIA	1
BRADYCARDIA	1
BRAIN DISORDER NOS	1
BRUISING	1
BUMPING INTO WALLS	1
CARDIAC ARREST	1
CARDIAC ENLARGEMENT	1
CARDIAC MURMUR	1
CARDIORESPIRATORY ARREST	1
CENTRAL VESTIBULAR DISORDER	1
CLOUDY EYE	1
COLLAPSE	1
COLLAPSE OF LEG	1
CONFUSION	1
CONJUNCTIVAL OEDEMA	1
CORNEAL DISORDER NOS	1
CORNEAL OEDEMA	1
CORTISOL HIGH, SERUM	1
CRYING	1
CRYSTALLURIA	1
DEAFNESS	1
DECREASED CHOLESTEROL (TOTAL)	1
DECREASED INTRA-OCULAR PRESSURE	1
DECREASED PULSE OXYGENATION	1

DRUG: FLURALANERSpecies: Dog
Route of Administration: ORAL

Sign :	Number of Times Reported :
DISCOMFORT NOS	1
DISORDER OF RED BLOOD CELL NOS	1
DRY SKIN	1
DULLNESS	1
DYSPNOEA	1
ELEVATED CREATINE-KINASE (CK)	1
ELEVATED RENAL PARAMETERS	1
ELEVATED SDMA (SYMMETRICAL DIMETHYLARGININE)	1
ELEVATED TEMPERATURE	1
ELEVATED TRIGLYCERIDE	1
ENLARGED LYMPH NODE	1
EOSINOPHILIA	1
EPILEPSY	1
EROSION	1
ERUCTATION	1
ERYTHEMA MULTIFORME	1
EXCESS TEAR FLOW	1
EXCESSIVE LICKING AND/OR GROOMING	1
EYE HAEMORRHAGE	1
EYE ITCHING	1
EYELID OEDEMA	1
FACE AND NECK SWELLING	1
FASCICULATION	1
FATIGUE	1
FEBRILE	1
FOAMING AT THE MOUTH	1

DRUG: FLURALANERSpecies: Dog
Route of Administration: ORAL

Sign :	Number of Times Reported :
FOETAL MUMMIFICATION	1
FOETAL RESORPTION	1
FOUND DEAD	1
GALL BLADDER INFLAMMATION	1
GASTRIC DISTENSION	1
GENERAL HAIR LOSS	1
GENERALISED SKIN REACTION	1
GLAZED EYE	1
GLUCOSURIA	1
HAIR CHANGE	1
HAIR LOSS NOS	1
HALITOSIS	1
HEAD BOBBING	1
HEAD SHAKE - BEHAVIOURAL DISORDER	1
HEAD TILT - NEUROLOGICAL DISORDER	1
HEART MURMUR	1
HEAT STROKE	1
HEPATIC NECROSIS	1
HEPATITIS	1
HEPATOPATHY	1
HIATUS HERNIA	1
HIGH BLOOD PRESSURE	1
HOT SPOT (PYOTRAUMATIC DERMATITIS)	1
HYPERADRENOCORTICISM	1
HYPERAEMIC MUCOUS MEMBRANE	1
HYPEREXCITATION	1

DRUG: FLURALANERSpecies: Dog
Route of Administration: ORAL

Sign :	Number of Times Reported :
HYPERKALEMIC CONDITION	1
HYPERNATREMIA	1
HYPERPIGMENTATION	1
HYPERTENSION	1
HYPOCALCAEMIC CONDITION	1
HYPOPHOSPHATAEMIA	1
HYPOPROTEINAEMIA	1
HYPOTENSION	1
ILEUS	1
IMPAIRED VISION	1
INCOORDINATION	1
INCREASED BORBORYGMUS	1
INCREASED BOWEL MOVEMENTS (FREQUENCY)	1
INCREASED HEART RATE	1
INCREASED PERCENTAGE RETICULOCYTES	1
INCREASED RESPIRATORY RATE	1
INCREASED URINE CONCENTRATION	1
INCREASED WEIGHT	1
INEFFECTIVE, FLEAS	1
INJECTION SITE SWELLING	1
INTERSTITIAL NEPHRITIS	1
INTERVERTEBRAL DISC DISEASE	1
INVOLUNTARY MOVEMENT	1
IRRITABILITY	1
JAUNDICE	1
JOINT ACHE	1

DRUG: FLURALANERSpecies: Dog
Route of Administration: ORAL

Sign :	Number of Times Reported :
JOINT EFFUSION	1
KNUCKLING	1
LACK OF COORDINATION	1
LACK OF EFFICACY (PARVOVIRUS)	1
LATERAL RECUMBENCY	1
LICKING	1
LIMPING	1
LIMPNESS	1
LOCALISED OEDEMA (NOT APPLICATION SITE)	1
LOCALISED PAIN NOS	1
LOSS OF CONDITION SCORE	1
LOSS OF VISION	1
LOW PLATELET COUNT	1
LOW WEIGHT GAIN	1
LUMP	1
LUNG OEDEMA	1
MAMMARY GLAND NEOPLASM NOS	1
MEGAOESOPHAGUS	1
MENTAL IMPAIRMENT NOS	1
MIOSIS	1
MUSCLE SPASM NOS	1
MUSCLE TREMOR	1
MUSCLE WEAKNESS NOS	1
MUSCULOSKELETAL PAIN	1
NASAL CONGESTION	1
NASAL DISCHARGE	1

DRUG: FLURALANERSpecies: Dog
Route of Administration: ORAL

Sign :	Number of Times Reported :
NEOPLASIA NOS	1
NERVOUS SYSTEM DISORDER NOS	1
NERVOUS SYSTEM NEOPLASM	1
NEUROLOGICAL SYMPTOMS NOS	1
NOT SLEEPING	1
OCULAR DISCHARGE	1
OEDEMA NOS	1
OEDEMA OF THE EXTREMITIES	1
ORAL BLEEDING	1
ORAL CAVITY DISORDER NOS	1
ORAL MASS	1
ORAL ULCERATION	1
ORGAN PETECHIAE	1
PADDLING	1
PAIN NOS	1
PARESIS	1
PARTIAL BLINDNESS	1
PHARYNGEAL DISORDER	1
PHOTOPHOBIA	1
PILOERECTION	1
PLEURAL EFFUSION	1
PNEUMONIA	1
PODODERMATITIS	1
POLYPHAGIA	1
PR-BLADDER, LESION(S)	1
PR-KIDNEY(S), LESION(S)	1

DRUG: FLURALANERSpecies: Dog
Route of Administration: ORAL

Sign :	Number of Times Reported :
PROLONGED ACTIVATED PARTIAL THROMBIN TIME (APTT)	1
PROLONGED BLEEDING NOS	1
PROLONGED ONE STAGE PROTHROMBIN TIME (OSPT)	1
PROSTATITIS	1
PR-PANCREAS, LESION(S)	1
PR-PROSTATE, LESION(S)	1
PURULENT LESION(S)	1
PYODERMA	1
RECTAL BLEEDING	1
RED BLOOD CELL DISORDER	1
RED MUCOSAE	1
REDUCED GROWTH RATE	1
REDUCED RESPONSES	1
RENAL DISORDER NOS	1
RENAL TUBULAR DISORDER	1
RESPIRATORY DISTRESS	1
RETINAL DISORDER NOS	1
SEDATION	1
SELF MUTILATION	1
SEPTICAEMIA	1
SHIVERING	1
SKIN ABSCESS	1
SKIN HAEMATOMA	1
SKIN INFLAMMATION NOS	1
SKIN OEDEMA	1
SKIN SORE	1

DRUG: FLURALANERSpecies: Dog
Route of Administration: ORAL

Sign :	Number of Times Reported :
SKIN SWELLING	1
SKIN TEXTURAL CHANGE	1
SKIN TUMOUR NOS	1
SKIN WARMTH	1
SLEEPINESS - SYSTEMIC DISORDER	1
SLOW HEART RATE	1
SMALL LIVER	1
SODIUM:POTASSIUM LOW, BLOOD	1
STATUS EPILEPTICUS	1
SUDDEN DEATH	1
SWELLING AROUND EYE	1
SWELLING NOS	1
SWOLLEN LIMB	1
SWOLLEN LYMPH NODE	1
TENSE ABDOMEN	1
THIRD EYELID PROTRUSION	1
THORACIC CAVITY DISORDER NOS	1
THROMBOCYTOSIS	1
TONGUE DISORDER NOS	1
TONGUE INFLAMMATION	1
TONIC-CLONIC SEIZURE	1
ULCERATIVE DERMATITIS	1
UNEXPLAINED DEATH	1
UNRESPONSIVE TO STIMULI	1
UNUSUAL STOOL COLOUR	1
URINARY TENESMUS	1

DRUG: FLURALANER

Species: Dog
Route of Administration: ORAL

Sign :	Number of Times Reported :
URINARY TRACT DISORDER NOS	1
URINE LEAKAGE	1
URTICARIAL RASH	1
UVEITIS	1
VESTIBULAR DISORDER NOS	1
WEIGHT GAIN	1

Species: Dog
Route of Administration: OTHER

Sign :	Number of Times Reported :
VOMITING	1

Species: Dog
Route of Administration: TOPICAL

Sign :	Number of Times Reported :
INEFFECTIVE, FLEAS	2
ABNORMAL TEST RESULT	1
ALOPECIA	1
DECREASED APPETITE	1
DIARRHOEA	1
LETHARGY	1
MOIST DERMATITIS	1
VOMITING	1

Species: Dog
Route of Administration: TRANSPLACENTAL

Sign :	Number of Times Reported :
DEATH BY EUTHANASIA	3
ABNORMAL NECROPSY FINDING	2
BIRTH DEFECT	2

DRUG: FLURALANER

Species: Dog
 Route of Administration: TRANSPLACENTAL

Sign :	Number of Times Reported :
CLEFT PALATE	2
PULMONARY OEDEMA	2
ANOREXIA	1
ELEVATED BUN	1
ELEVATED CREATININE	1
LETHARGY	1
RENAL FAILURE	1
SUCKLING DISORDER NOS	1
UNEXPLAINED DEATH	1
WEIGHT LOSS	1

Species: Dog
 Route of Administration: UNKNOWN

Sign :	Number of Times Reported :
LETHARGY	1
PSEUDOPREGNANCY	1
STILLBIRTH	1
VOMITING	1

Species: Human
 Route of Administration: ORAL

Sign :	Number of Times Reported :
ECZEMA	1
GENERALISED RASH	1

Species: Human
 Route of Administration: OTHER

Sign :	Number of Times Reported :
APPLICATION SITE SKIN CHANGE NOS	1
BAD TASTE	1

DRUG: FLURALANER

Species: Human
Route of Administration: OTHER

Sign :	Number of Times Reported :
COUGH	1

Species: Human
Route of Administration: TOPICAL

Sign :	Number of Times Reported :
APPLICATION SITE SKIN CHANGE NOS	8
FACIAL RASH	2
APPLICATION SITE ERYTHEMA	1
BURNING SENSATION (SKIN)	1
FEELINGS OF WEAKNESS	1
HEADACHE	1

Species: Human
Route of Administration: UNKNOWN

Sign :	Number of Times Reported :
HEADACHE	1
HIVES	1
RASH	1
STOMACH UPSET	1
SWOLLEN LIP	1
TASTE ALTERATION	1

Species: Other Birds
Route of Administration: ORAL

Sign :	Number of Times Reported :
ABNORMAL TEST RESULT	1
CIRCLING	1
CONFUSION	1
ENCEPHALITIS	1
GAIT ABNORMALITY	1

DRUG: FLURALANER

Species: Other Birds
Route of Administration: ORAL

Sign :	Number of Times Reported :
HEAD TILT - EAR DISORDER	1