

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 2/26/2018. The search parameters were:

<u>Active ingredient(s):</u>	afoxolaner, fluralaner and sarolaner
<u>Reports received:</u>	From 10/1/2017 through 12/31/2017
<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.

### **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 use in **dogs** only and topical use in **dogs** and **cats** only. For the time period of the ADE database search (10/1/2017 through 12/31/2017), there were a total of 737 ADE reports received for afoxolaner for dogs, a total of 1191 ADE reports received for fluralaner for dogs, and a total of 429 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:

<b>Species</b>	<b># Afoxolaner reports</b>	<b># Fluralaner reports</b>	<b># Sarolaner reports</b>
Dog	737	1191	429
Cat	2	315	4
Human (accidental exposures)	2	36	2
Wolf	1		
Tiger		1	
Total # ADE reports, all species	742	1543	435

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.

February 26, 2018

- 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 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 : 01-Oct-2017 -thru- 31-Dec-2017

Included 1932a cases = : True

Included Medicated Feed cases = : False

## DRUG: FLURALANER

Species: Cat  
Route of Administration: ORAL

Sign :	Number of Times Reported :
ANAEMIA NOS	1
APPLICATION SITE HAIR LOSS	1
ARRHYTHMIA	1
DEATH	1
DECREASED PACKED CELL VOLUME (PCV)	1
ELEVATED ALT	1
ELEVATED BUN	1
HIND LIMB PARESIS	1
HYPERGLYCAEMIA	1
LACK OF EFFICACY (ECTOPARASITES)	1
LETHARGY	1
LEUCOCYTOSIS	1
MEDICATION ERROR	1
TIREDDNESS	1
WEAKNESS	1
WEIGHT LOSS	1

Species: Cat  
Route of Administration: TOPICAL

Sign :	Number of Times Reported :
LACK OF EFFICACY (ECTOPARASITES)	67
APPLICATION SITE HAIR LOSS	53

## DRUG: FLURALANER

Species: Cat  
Route of Administration: TOPICAL

Sign :	Number of Times Reported :
LETHARGY	46
EMESIS (MULTIPLE)	29
APPLICATION SITE ALOPECIA	24
BEHAVIOURAL DISORDER NOS	22
APPLICATION SITE GREASY FUR	21
DECREASED APPETITE	17
VOMITING	17
FOAMING AT THE MOUTH	16
PRURITUS	14
VOCALISATION	14
DIARRHOEA	13
HYPERSALIVATION	13
AGITATION	12
APPLICATION SITE HAIR CHANGE	12
HIDING	12
DROOLING	11
ANOREXIA	10
HYPERACTIVITY	9
FEVER	8
PANTING	8
SCRATCHING	8
APPLICATION SITE SCAB	7
EXCESSIVE LICKING AND/OR GROOMING	7
NOT EATING	7
APPLICATION SITE REDDENING	6
SKIN SCAB	6

**DRUG: FLURALANER**Species: Cat  
Route of Administration: TOPICAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
TREMOR	6
TWITCHING	6
WEIGHT LOSS	6
APPLICATION SITE IRRITATION	5
APPLICATION SITE ITCHING	5
APPLICATION SITE PRURITUS	5
DISCOMFORT NOS	5
ITCHING	5
SEIZURE NOS	5
ABNORMAL TEST RESULT	4
AGGRESSION	4
APPLICATION SITE ERYTHEMA	4
APPLICATION SITE SELF TRAUMA	4
DECREASED PACKED CELL VOLUME (PCV)	4
DEHYDRATION	4
GENERAL HAIR LOSS	4
INAPPROPRIATE URINATION	4
ABNORMAL BREATHING	3
APPLICATION SITE SCRATCHING	3
APPLICATION SITE ULCER	3
DECREASED DRINKING	3
DECREASED HAEMOGLOBIN	3
ELEVATED ALT	3
HAIR LOSS NOS	3
HYPERGLYCAEMIA	3
INAPPETENCE	3

**DRUG: FLURALANER**Species: Cat  
Route of Administration: TOPICAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
NOT DRINKING	3
SELF TRAUMA	3
ALOPECIA GENERAL	2
ANAPHYLAXIS	2
APPLICATION SITE BLEEDING	2
APPLICATION SITE CRUST	2
APPLICATION SITE LESION	2
APPLICATION SITE RESIDUE	2
ATAXIA	2
BLOOD IN URINE	2
CONSTIPATION	2
CRUST	2
DEATH	2
DECREASED ACTIVITY	2
DECREASED RED BLOOD CELL COUNT	2
EAR TWITCHING	2
ELEVATED BUN	2
ELEVATED CREATININE	2
ELEVATED GLOBULINS	2
ELEVATED SAP	2
ELEVATED TOTAL BILIRUBIN	2
ERYTHEMA	2
FACIAL SWELLING	2
FASCICULATION	2
FLAKING SKIN	2
FREQUENT URINATION	2

**DRUG: FLURALANER**Species: Cat  
Route of Administration: TOPICAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
GENERALISED ITCHING	2
HEAD SHAKE - BEHAVIOURAL DISORDER	2
HEAD SHAKE - EAR DISORDER	2
HEAD TREMOR	2
HYPERPROTEINAEMIA	2
HYPOALBUMINAEMIA	2
ITCHY SKIN	2
LABOURED BREATHING	2
LEUCOCYTOSIS	2
LICKING	2
LOCALISED HAIR LOSS	2
MOIST DERMATITIS	2
MYDRIASIS	2
NASAL DISCHARGE	2
PAIN NOS	2
PRODUCT PROBLEM	2
RELUCTANT TO MOVE	2
RUBBING	2
SNEEZING	2
TACHYPNOEA	2
TREMOR OF LIMB	2
WALKING DIFFICULTY	2
ABNORMAL CYTOLOGY	1
ABNORMAL NECROPSY FINDING	1
ABNORMAL POSTURE	1
ABNORMAL RADIOGRAPH FINDING	1



## DRUG: FLURALANER

Species: Cat  
Route of Administration: TOPICAL

Sign :	Number of Times Reported :
ACNE	1
ACUTE RENAL FAILURE	1
ALOPECIA	1
ALOPECIA LOCAL	1
ANAL AND RECTAL DISORDER NOS	1
ANAL IRRITATION	1
APPLICATION SITE BLISTER	1
APPLICATION SITE BURN	1
APPLICATION SITE DERMATITIS	1
APPLICATION SITE EXCORIATION	1
APPLICATION SITE HAIR COAT DISCOLOURATION	1
APPLICATION SITE INFECTION	1
APPLICATION SITE PAIN	1
APPLICATION SITE REACTION NOS	1
APPLICATION SITE SWELLING	1
APPLICATION SITE THICKENING	1
APPLICATION SITE TWITCHING	1
BALANCE IMPAIRED	1
BLEPHAROSPASM	1
BLOOD IN FAECES	1
BLOOD IN VOMIT	1
BLOODY DIARRHOEA	1
BREATHING DIFFICULTY	1
CERVICAL VENTROFLEXION	1
CHRONIC RENAL FAILURE	1
COLLAPSE	1

**DRUG: FLURALANER**Species: Cat  
Route of Administration: TOPICAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
CONJUNCTIVAL IRRITATION	1
CONJUNCTIVITIS	1
COUGH	1
CRYING	1
CRYSTALLURIA	1
DEAFNESS	1
DEATH BY EUTHANASIA	1
DECREASED BODY TEMPERATURE	1
DECREASED CHOLESTEROL (TOTAL)	1
DEPRESSION	1
DILATED PUPILS	1
DISORIENTATION	1
DISTRESS	1
DRINKING A LOT	1
DRY MOUTH	1
DRY MUCOUS MEMBRANE	1
DRY SKIN	1
EAR INFECTION NOS	1
EAR IRRITATION	1
ELEVATED AMYLASE	1
ELEVATED AST	1
ELEVATED CREATINE-KINASE (CK)	1
ELEVATED LIPASE	1
ELEVATED SDMA (SYMMETRICAL DIMETHYLARGININE)	1
ELEVATED TRIGLYCERIDE	1
ENLARGED LYMPH NODE	1

**DRUG: FLURALANER**

Species: Cat  
Route of Administration: TOPICAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
ERYTHEMATOUS RASH	1
EXCESSIVE THIRST	1
EXCORIATION	1
EYE IRRITATION	1
FALLING	1
GAIT ABNORMALITY	1
GENERAL PAIN	1
GENERALISED WEAKNESS	1
HAIR COAT DISCOLOURATION	1
HAIR SHEDDING	1
HEAD TILT - EAR DISORDER	1
HIVES	1
HYPERAESTHESIA	1
HYPOCALCAEMIC CONDITION	1
HYPOCHLORAEMIA	1
ICTERUS	1
IMMUNE MEDIATED HAEMOLYTIC ANAEMIA	1
INAPPROPRIATE DEFECATION	1
INCOORDINATION	1
INEFFECTIVE, FLEAS	1
ITCHY EARS	1
JAUNDICE	1
JOINT STIFFNESS	1
LACK OF COORDINATION	1
LATERAL RECUMBENCY	1
LISTLESS	1

**DRUG: FLURALANER**Species: Cat  
Route of Administration: TOPICAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
LOCALISED PAIN NOS	1
LOW PLATELET COUNT	1
LYMPHOPENIA	1
MEDICATION ERROR	1
MONOCYTOSIS	1
MUCOUS STOOL	1
MURMUR	1
MUSCLE TREMOR	1
MUSCLE WASTING	1
MYOCLONIC JERK	1
NEUTROPHILIA	1
OLIGURIA	1
ORAL ULCERATION	1
PACING	1
PARTIAL ANOREXIA	1
PINNAE DISORDER	1
PINNAL REDDENING	1
POLYDIPSIA	1
POLYURIA	1
POOR COAT CONDITION	1
PROPRIOCEPTION DEFICIT	1
PULMONARY CONGESTION	1
PULMONARY EMPHYSEMA	1
PYURIA	1
QUADRIPARESIS	1
RECTAL BLEEDING	1

**DRUG: FLURALANER**Species: Cat  
Route of Administration: TOPICAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
REDDENING OF THE SKIN	1
REGENERATIVE ANAEMIA	1
REGURGITATION	1
RENAL DISORDER NOS	1
RESPIRATORY TRACT INFECTION NOS	1
RESTLESSNESS	1
RETCHING	1
SCALE	1
SEBORRHOEA	1
SKIN INFLAMMATION NOS	1
SKIN IRRITATION	1
SKIN LESION NOS	1
SKIN WARMTH	1
SQUINTING	1
STRIDOR (UPPER RESPIRATORY; FOR LOWER RESPIRATORY SEE ALSO BRONCHIAL RALE)	1
THIRD EYELID PROLAPSE	1
THROMBOCYTOPENIA	1
ULCERATIVE DERMATITIS	1
UNABLE TO FOCUS	1
UNABLE TO RISE	1
UNABLE TO STAND	1
UNCLASSIFIABLE ADVERSE EVENT	1
UNCOMFORTABLE	1
UNSTEADY GAIT	1
URINARY TRACT INFECTION	1

**DRUG: FLURALANER**

Species: Cat  
Route of Administration: TOPICAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
VASCULITIS	1
WOUND	1

Species: Dog  
Route of Administration: MISSING

<b>Sign :</b>	<b>Number of Times Reported :</b>
DEATH	1
SEIZURE NOS	1

Species: Dog  
Route of Administration: ORAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
VOMITING	504
LACK OF EFFICACY (ECTOPARASITES)	405
EMESIS (MULTIPLE)	151
LETHARGY	137
DIARRHOEA	102
SEIZURE NOS	62
ABNORMAL TEST RESULT	51
BEHAVIOURAL DISORDER NOS	46
DECREASED APPETITE	41
NOT EATING	34
ELEVATED SAP	31
ANOREXIA	30
SHAKING	30
BLOODY DIARRHOEA	29
WEIGHT LOSS	25
ELEVATED ALT	24
ATAXIA	23

## DRUG: FLURALANER

Species: Dog  
Route of Administration: ORAL

Sign :	Number of Times Reported :
ELEVATED BUN	23
PANTING	23
ABNORMAL RADIOGRAPH FINDING	22
DEATH BY EUTHANASIA	19
NEUTROPHILIA	19
INAPPETENCE	18
PRURITUS	18
LEUCOCYTOSIS	17
MONOCYTOSIS	17
DEATH	16
HYPERPHOSPHATAEMIA	16
ABNORMAL ULTRASOUND FINDING	15
ELEVATED CREATININE	15
SCRATCHING	15
LOOSE STOOL	14
ABDOMINAL PAIN	13
ELEVATED AST	13
FALLING	13
HYPERGLYCAEMIA	13
LATERAL RECUMBENCY	13
POLYDIPSIA	13
RECUMBENCY	13
COUGH	12
DEHYDRATION	12
FEVER	12
HYPOALBUMINAEMIA	12

## DRUG: FLURALANER

Species: Dog  
Route of Administration: ORAL

Sign :	Number of Times Reported :
INAPPROPRIATE URINATION	12
NOT DRINKING	12
CRYING	11
ELEVATED GLOBULINS	11
ELEVATED LIPASE	11
LACK OF EFFICACY	11
NAUSEA	11
PICA NOS	11
RELUCTANT TO MOVE	11
HYPOGLYCAEMIA	10
MUSCLE SHAKING	10
PADDLING	10
PANCREATITIS	10
PRODUCT PROBLEM	10
RESTLESSNESS	10
RETCHING	10
ELEVATED GAMMA-GLUTAMYL TRANSFERASE (GGT)	9
ELEVATED TOTAL BILIRUBIN	9
HAEMATURIA	9
LAMENESS	9
MALaise	9
POLYURIA	9
THROMBOCYTOPENIA	9
WEAKNESS	9
BILIRUBINURIA	8
DECREASED PACKED CELL VOLUME (PCV)	8



**DRUG: FLURALANER**

Species: Dog  
Route of Administration: ORAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
ELEVATED AMYLASE	8
ELEVATED CHOLESTEROL (TOTAL)	8
FLATULENCE	8
HYPONATREMIA	8
LYMPHOPENIA	8
PROTEINURIA	8
THROMBOCYTOSIS	8
TREMBLING	8
ABNORMAL CYTOLOGY	7
AGITATION	7
ANXIETY	7
DEPRESSION	7
DRINKING A LOT	7
GAIT ABNORMALITY	7
HYPERSALIVATION	7
INCREASED PACKED CELL VOLUME (PCV)	7
LIVER DISORDER NOS	7
PACING	7
PALE MUCOUS MEMBRANE	7
PROPRIOCEPTION DEFICIT	7
STIFFNESS NOS	7
TACHYCARDIA	7
TREMOR	7
URINARY TRACT INFECTION	7
VOCALISATION	7
DECREASED CHOLESTEROL (TOTAL)	6

**DRUG: FLURALANER**Species: Dog  
Route of Administration: ORAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
DECREASED DRINKING	6
DISTENSION OF ABDOMEN	6
DROOLING	6
ELEVATED CREATINE-KINASE (CK)	6
ERYTHEMA	6
HIVES	6
HYPOPROTEINAEMIA	6
INAPPROPRIATE DEFECATION	6
INVOLUNTARY MOVEMENT	6
ITCHING	6
LABOURED BREATHING	6
UNABLE TO STAND	6
URINE ABNORMALITIES NOS	6
APPETITE LOSS	5
BREATHING DIFFICULTY	5
DECREASED HAEMOGLOBIN	5
DECREASED RED BLOOD CELL COUNT	5
EAR INFECTION NOS	5
GAGGING	5
GENERAL HAIR LOSS	5
HOT SPOT (PYOTRAUMATIC DERMATITIS)	5
HYPERKALEMIC CONDITION	5
HYPOCHLORAEMIA	5
HYPOTHYROIDISM	5
INCREASED PERCENTAGE RETICULOCYTES	5
INTESTINAL DISORDER NOS	5

## DRUG: FLURALANER

Species: Dog  
Route of Administration: ORAL

Sign :	Number of Times Reported :
JAUNDICE	5
LEUCOPENIA	5
LICKING	5
LOCALISED PAIN NOS	5
MUSCLE SPASM NOS	5
MUSCULOSKELETAL DISORDER NOS	5
NEUROLOGICAL SIGNS NOS	5
PAIN NOS	5
SKIN IRRITATION	5
STUMBLING GAIT	5
TWITCHING	5
URINARY INCONTINENCE	5
ABNORMAL MOVEMENT NOS	4
ABNORMAL POSTURE NOS	4
ABNORMAL PUPIL LIGHT REFLEX	4
ADIPSIA	4
AGGRESSION	4
ANAEMIA NOS	4
ARCHED BACK	4
BITING	4
COLLAPSE NOS	4
COLLAPSE OF LEG	4
CRUST	4
CRYSTALLURIA	4
DECREASED URINE CONCENTRATION	4
DIGESTIVE TRACT DISORDER NOS	4

## DRUG: FLURALANER

Species: Dog  
Route of Administration: ORAL

Sign :	Number of Times Reported :
DILATED PUPILS	4
DISCOMFORT NOS	4
DISORIENTATION	4
DRY MUCOUS MEMBRANE	4
DRY SKIN	4
ELEVATED TRIGLYCERIDE	4
EYE DISORDER NOS	4
FOAMING AT THE MOUTH	4
FREQUENT URINATION	4
GENERALISED ITCHING	4
GENERALISED SKIN REACTION	4
GLUCOSURIA	4
HAEMATEMESIS	4
HYPERCHLORAEMIA	4
HYPERNATREMIA	4
HYPOTHERMIA	4
INCREASED BORBORYGMUS	4
INVERSION OF ALBUMIN/GLOBULIN RATIO	4
LIMB WEAKNESS	4
LOCALISED HAIR LOSS	4
MEDICATION ERROR	4
MUCOUS STOOL	4
MUSCLE TREMOR	4
POLYCYTHAEMIA	4
RASH	4
RENAL DISORDER NOS	4

**DRUG: FLURALANER**

Species: Dog  
Route of Administration: ORAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
RUBBING	4
SKIN SCAB	4
SKIN WARMTH	4
SLEEPINESS - SYSTEMIC DISORDER	4
TENSE MUSCLES	4
UNCOMFORTABLE	4
WALKING DIFFICULTY	4
WEIGHT GAIN	4
ABDOMINAL EFFUSION	3
ABNORMAL BREATHING	3
ABNORMAL NECROPSY FINDING	3
ALLERGIC DERMATITIS	3
BACTERIAL SKIN INFECTION NOS	3
BLINDNESS	3
BLOOD IN FAECES	3
BLOOD IN URINE	3
BLOOD IN VOMIT	3
BRADYCARDIA	3
CATARACT	3
CIRCLING	3
CLAW / HOOF / NAIL DISORDER NOS	3
CLOUDY EYE	3
COLLAPSE	3
DECREASED ACTIVITY	3
DENTAL CALCULUS	3
DENTAL DISEASE	3

**DRUG: FLURALANER**

Species: Dog  
Route of Administration: ORAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
DIABETES MELLITUS	3
ELEVATED BILE ACIDS	3
ELEVATED RENAL PARAMETERS	3
ELEVATED SDMA (SYMMETRICAL DIMETHYLARGININE)	3
EPILEPTIC SEIZURE	3
FACIAL SWELLING	3
FLUID IN ABDOMEN NOS	3
FLY BITING BEHAVIOUR	3
HEAD BOBBING	3
HEAD TILT - NEUROLOGICAL DISORDER	3
HEAD TREMOR	3
HEART MURMUR	3
HYPERPROTEINAEMIA	3
HYPOCALCAEMIC CONDITION	3
HYPOKALEAEMIA	3
HYPOPHOSPATAEMIA	3
IMMUNE MEDIATED HAEMOLYTIC ANAEMIA	3
INVOLUNTARY DEFECATION	3
ITCHY SKIN	3
LACK OF AWARENESS	3
LIP LICKING	3
LOCALISED RASH	3
LOSS OF CONSCIOUSNESS	3
LOW PLATELET COUNT	3
LUMBAR PAIN	3
LUMP	3

**DRUG: FLURALANER**Species: Dog  
Route of Administration: ORAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
MALODOUR	3
MELAENA	3
MOIST DERMATITIS	3
MUSCULOSKELETAL PAIN	3
OCULAR DISCHARGE	3
OTITIS EXTERNA	3
PLATELET DISORDER NOS	3
PYURIA	3
RED BLOOD CELL DISORDER	3
REDUCED RESPONSES	3
RENAL FAILURE	3
SELF TRAUMA	3
SHIVERING	3
SKIN DISORDERS NOS	3
SKIN SORE	3
SKIN ULCER	3
SMALL LIVER	3
SPLENOMEGALY	3
STIFF GAIT	3
STIFFNESS LIMB	3
TACHYPNOEA	3
TARRY OR BLACK STOOL	3
TREMOR OF LIMB	3
UNABLE TO JUMP	3
UNCONSCIOUS	3
UNRESPONSIVE TO STIMULI	3

**DRUG: FLURALANER**

Species: Dog  
Route of Administration: ORAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
ABDOMINAL DISCOMFORT	2
ABNORMAL MENACE REFLEX TEST	2
ABNORMAL POSTURE	2
ABNORMAL RED BLOOD CELL	2
ABNORMAL STOOL COLOURATION	2
ALKALINE URINE	2
ALLERGIC PRURITUS	2
ALOPECIA GENERAL	2
ANAL SAC DISORDER	2
AZOTAEMIA	2
BARKING	2
BONE AND JOINT DISORDER NOS	2
BRAIN DISORDER NOS	2
BUMPING INTO WALLS	2
COLITIS	2
COMA	2
CONFUSION	2
CONJUNCTIVITIS	2
CORNEAL DISORDER NOS	2
CYANOSIS	2
DECREASED BODY TEMPERATURE	2
DENTAL PLAQUE	2
DISCOLOURED URINE	2
DISORIENTED STATE	2
DULL	2
DULLNESS	2



## DRUG: FLURALANER

Species: Dog  
Route of Administration: ORAL

Sign :	Number of Times Reported :
EAR DISCHARGE	2
ECCHYMOSIS	2
ELECTROLYTE DISORDER	2
EOSINOPHILIA	2
ERYTHEMATOUS RASH	2
EXOCRINE PANCREATIC INSUFFICIENCY	2
FASCICULATION	2
FOUND DEAD	2
GALL BLADDER & BILE DUCT DISORDER NOS	2
GASTROINTESTINAL FOREIGN BODY NOS	2
GENERAL PAIN	2
GENERALISED WEAKNESS	2
HAEMORRHAGIC GASTROENTERITIS	2
HARSH LUNG SOUNDS	2
HIND LIMB PARESIS	2
HYPERCALCAEMIA	2
HYPOKALEMIC CONDITION	2
HYPOSTHENURIA	2
INCREASED SEIZURE FREQUENCY	2
INCREASED WEIGHT	2
INTERVERTEBRAL DISC DISEASE	2
ISOSTHENURIA	2
ITCHY EARS	2
JOINT PAIN	2
LACERATION	2
LACK OF RESPONSE TO OWNER	2

**DRUG: FLURALANER**Species: Dog  
Route of Administration: ORAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
LOSS OF VISION	2
LOW VISION	2
MENTAL IMPAIRMENT NOS	2
MUSCLE WEAKNESS NOS	2
NASAL CAVITY DISORDER NOS	2
NOT SLEEPING	2
NYSTAGMUS	2
OPISTHOTONUS	2
PAPULE	2
PARALYSIS	2
PARTIAL ANOREXIA	2
PNEUMONIA	2
POLYARTHRITIS	2
POLYPHAGIA	2
PTYALISM	2
REDDENING OF THE SKIN	2
REDUCED GLOBULINS	2
RETINAL DISORDER NOS	2
RIGIDITY	2
SHALLOW BREATHING	2
SICK EUTHYROID SYNDROME	2
SKIN LESION NOS	2
SKIN PETECHIAE	2
SLEEP DISTURBANCE NOS	2
STAGGERING	2
STAR-GAZING	2

**DRUG: FLURALANER**

Species: Dog  
Route of Administration: ORAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
STOMACH UPSET	2
SUDDEN DEATH	2
SWOLLEN EYE	2
SWOLLEN FACE	2
SWOLLEN FEET	2
TENSE ABDOMEN	2
TONGUE DISORDER NOS	2
ABDOMINAL CAVITY DISORDER NOS	1
ABDOMINAL CAVITY HAEMORRHAGE	1
ABDOMINAL CAVITY HERNIA	1
ABDOMINAL MASS	1
ACIDOSIS	1
ALLERGIC REACTION	1
ALLERGY NOS	1
ALOPECIA	1
ALOPECIA LOCAL	1
ALOPECIA NOS	1
ANISOCORIA	1
APPREHENSION	1
ARTHRITIS	1
AUTOIMMUNE DISORDER NOS	1
BASOPHILIA	1
BIRTH DEFECT	1
BLISTERING	1
BLOATED STOMACH	1
BRONCHOPNEUMONIA	1

**DRUG: FLURALANER**Species: Dog  
Route of Administration: ORAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
BRUISING	1
BUN LOW, BLD	1
CARDIAC ARREST	1
CARDIAC ENLARGEMENT	1
CARDIOPATHY	1
CARTILAGE DEGENERATION	1
CHATTERING OF TEETH	1
CIRCULATORY DISORDER NOS	1
COGNITIVE DISORDER NOS	1
COLD FEELING OF EXTREMITY	1
CONFUSED	1
CONGENITAL SKIN DISORDER NOS	1
CONGESTIVE HEART FAILURE	1
CONSTIPATION	1
CONVULSION	1
CORNEAL ULCER	1
CUSHINGS DISEASE - ADRENAL DEPENDENT	1
DEAFNESS	1
DECREASED BOWEL MOVEMENTS	1
DECREASED PULSE OXYGENATION	1
DEPRESSED REFLEXES	1
DERMAL CYST(S)	1
DERMAL THICKENING	1
DERMATITIS	1
DIABETIC KETONURIA	1
DIGESTIVE TRACT HYPERMOTILITY	1

**DRUG: FLURALANER**Species: Dog  
Route of Administration: ORAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
DISORDER OF GASTROINTESTINAL FLORA	1
DRUNKEN GAIT	1
DRY NOSE	1
DYSPHAGIA	1
DYSPNOEA	1
EAR CANAL ERYTHEMA	1
EAR CANAL OEDEMA	1
EAR PAIN	1
EAR PRURITUS	1
ELEVATED PROTEIN:CREATININE RATIO	1
ELEVATED TEMPERATURE	1
EMESIS	1
ENLARGED KIDNEY(S)	1
ENLARGED LIVER	1
ENLARGED LYMPH NODE(S)	1
ENTERITIS	1
EPILEPSY	1
EPISTAXIS	1
EXCESSIVE LICKING AND/OR GROOMING	1
EXCESSIVE THIRST	1
EXCORIATION	1
EXOPHTHALMIA	1
EYE INFLAMMATION NOS	1
EYE PAIN	1
EYE REDNESS	1
EYELID LUMP	1

**DRUG: FLURALANER**Species: Dog  
Route of Administration: ORAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
FACE AND NECK SWELLING	1
FACIAL OEDEMA	1
FACIAL PARALYSIS	1
FEBRILE	1
FEET SHIFTING	1
FLACCID MUSCLES	1
FLACCID PARALYSIS	1
FLAKING SKIN	1
FOAM IN THE NOSE	1
FOLLICULITIS	1
FOOD REFUSAL	1
GASTRIC BLOAT	1
GASTRIC DISTENSION	1
GASTROENTERITIS	1
GENERALISED RASH	1
GINGIVAL HYPERPLASIA	1
GINGIVITIS	1
GLAZED EYE	1
GROANING	1
GUM DISORDER NOS	1
HAEMOCONCENTRATION	1
HAIR LOSS NOS	1
HAIR SHEDDING	1
HALLUCINATION	1
HEAD DOWN	1
HEAD SHAKE - BEHAVIOURAL DISORDER	1

**DRUG: FLURALANER**

Species: Dog  
Route of Administration: ORAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
HEAD SHAKE - EAR DISORDER	1
HEART FAILURE	1
HEPATIC NEOPLASM	1
HEPATITIS	1
HEPATO-BILIARY DISORDER NOS	1
HEPATOPATHY	1
HICCUP	1
HIDING	1
HIND LIMB PARALYSIS	1
HYPERACTIVITY	1
HYPERAESTHESIA	1
HYPERTENSION	1
HYPERTHERMIA	1
HYPOADRENOCORTICISM	1
HYPOPARATHYROIDISM	1
HYPOPIGMENTATION	1
HYPOSENSITIVITY TO PAIN	1
ICTERUS	1
ILEUS	1
IMPAIRED CONSCIOUSNESS	1
IMPAIRED GASTRIC FUNCTION	1
IMPAIRED HEARING	1
IMPAIRED SWALLOWING	1
INCOORDINATION	1
INCREASED BOWEL MOVEMENTS (FREQUENCY)	1
INCREASED HEART RATE	1

**DRUG: FLURALANER**

Species: Dog  
Route of Administration: ORAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
INCREASED INTRA-OCULAR PRESSURE	1
INCREASED RESPIRATORY RATE	1
INFERTILITY NOS	1
INJECTED SCLERA	1
INJECTION SITE SWELLING	1
IRRITABILITY	1
ITCHY RASH	1
JAW DISORDER	1
JEJUNITIS	1
JOINT INFLAMMATION	1
JOINT LIGAMENT DISORDER NOS	1
JOINT OEDEMA	1
JOINT PAIN NOS	1
JOINT STIFFNESS	1
JOINT SWELLING	1
KERATITIS	1
KERATOCONJUNCTIVITIS SICCA	1
KNUCKLING	1
LACK OF COORDINATION	1
LACK OF EFFICACY (ENDOPARASITES)	1
LACK OF EFFICACY (HEARTWORM)	1
LARGE PLATELETS	1
LENS DISORDER NOS	1
LENS OPACITY	1
LICK GRANULOMA	1
LIGAMENT RUPTURE	1



**DRUG: FLURALANER**

Species: Dog  
Route of Administration: ORAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
LIMPING	1
LIP ERYTHEMA	1
LIP OEDEMA	1
LIPAEMIA	1
LIPOMA	1
LISTLESS	1
LIVER FAILURE	1
LOCAL SWELLING (NOT APPLICATION SITE)	1
LOCALISED ITCHING	1
LOSS OF BOWEL CONTROL	1
LOSS OF CONDITION	1
LOSS OF VOLUNTARY MOVEMENT	1
LYMPHADENOPATHY	1
LYMPHOCYTOSIS	1
MILK DROP	1
MIOSIS	1
MISCARRIAGE	1
MISCELLANEOUS EATING DISORDER NOS	1
MOUTH PAIN	1
MUSCLE ATROPHY	1
MUSCLE RIGIDITY	1
MUSCLE WASTING	1
NASAL DISCHARGE	1
NERVE DAMAGE NOS	1
NEUROPATHY NOS	1
NEUTROPENIA	1

**DRUG: FLURALANER**

Species: Dog  
Route of Administration: ORAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
NOT URINATING	1
OPEN MOUTH BREATHING	1
OPTIC DISC OEDEMA	1
OPTIC NERVE DISORDER	1
ORAL BLEEDING	1
OTHER BLOOD DISORDER NOS	1
OTHER EAR DISORDER NOS	1
OTHER IMMUNE SYSTEM DISORDER NOS	1
PANCREAS DISORDER	1
PARTIAL ADIPSIA	1
PAWING	1
PEELING SKIN	1
PERITONITIS	1
PETECHIAE NOS	1
PETIT MAL EPILEPSY	1
PILOERECTION	1
PIMPLES	1
PINNAL REDDENING	1
PLEURAL EFFUSION	1
PNEUMOTHORAX	1
PODODERMATITIS	1
POLLAKIURIA	1
PREPUTIAL DISCHARGE	1
PROLONGED CAPILLARY REFILL TIME	1
PROLONGED ONE STAGE PROTHROMBIN TIME (OSPT)	1
PULMONARY HAEMORRHAGE	1

**DRUG: FLURALANER**

Species: Dog  
Route of Administration: ORAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
PUSTULES	1
PYODERMA	1
PYREXIA	1
QUADRIPARESIS	1
RECTAL HAEMORRHAGE	1
RECTAL PROLAPSE	1
REGURGITATION	1
RENAL INSUFFICIENCY	1
RESPIRATORY TRACT DISORDER NOS	1
RETINAL DEGENERATION	1
RIGIDITY OF LIMBS	1
SALIVARY STAINING	1
SCALE	1
SCOOTING	1
SEBORRHOEA	1
SEDATION	1
SENSORY ABNORMALITY NOS	1
SINUS CONGESTION	1
SKIN INFLAMMATION NOS	1
SKIN SLOUGH	1
SKIN TEXTURAL CHANGE	1
SLEEPINESS - NEUROLOGICAL DISORDER	1
SMELLY BREATH	1
SNEEZING	1
SNIFFING	1
SPASM	1

**DRUG: FLURALANER**Species: Dog  
Route of Administration: ORAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
SPLENIC NEOPLASM	1
SQUINTING	1
STRAINING TO DEFECATE	1
STRESS LEUKOGRAM	1
STUPOR	1
SUPPURATIVE DERMATITIS	1
SWELLING NOS	1
SWOLLEN JOINT	1
SWOLLEN LIMB	1
SWOLLEN LIP	1
THIRD EYELID EXTRUSION	1
TIREDNESS	1
TONIC-CLONIC SEIZURE	1
TORN LIGAMENT	1
TRANSIENT BLINDNESS	1
TRAUMA NOS	1
TRIGEMINUS PARALYSIS	1
ULCERATIVE DERMATITIS	1
UNABLE TO RISE	1
UNCLASSIFIABLE ADVERSE EVENT	1
UNUSUAL STOOL COLOUR	1
URINARY BLADDER DISORDER NOS	1
URINATION	1
URTICARIA	1
URTICARIAL ERYTHEMA	1
VESTIBULAR DISORDER NOS	1

**DRUG: FLURALANER**

Species: Dog  
Route of Administration: ORAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
VITAMIN DISORDER	1
VOICE ALTERATION	1
WART	1
WEAK PULSE	1
WHEEZING	1
YELLOW MUCOUS MEMBRANES	1

Species: Dog  
Route of Administration: OTHER

<b>Sign :</b>	<b>Number of Times Reported :</b>
LACK OF EFFICACY (ECTOPARASITES)	1

Species: Dog  
Route of Administration: TOPICAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
DENTAL DISEASE	1
DISORDER OF GASTROINTESTINAL FLORA	1
HEART MURMUR	1
INCREASED SEIZURE FREQUENCY	1
LACK OF EFFICACY (ECTOPARASITES)	1
RIGIDITY OF LIMBS	1
SEIZURE NOS	1
STERNOABDOMINAL RECUMBENCY	1
TENSE MUSCLES	1

Species: Dog  
Route of Administration: UNKNOWN

<b>Sign :</b>	<b>Number of Times Reported :</b>
SENSORY ABNORMALITY NOS	1

**DRUG: FLURALANER**

Species: Human  
Route of Administration: TOPICAL

<b>Sign :</b>	<b>Number of Times Reported :</b>
APPLICATION SITE SKIN CHANGE NOS	32
APPLICATION SITE REDDENING	1
BLISTERING	1
DIFFICULTY SLEEPING	1
DIZZINESS	1
EYE IRRITATION	1
HIVES	1
INCREASED HEART RATE	1
ITCHY SKIN	1
LOCALISED RASH	1
NASAL CONGESTION	1
RASH	1
RESPIRATORY TRACT IRRITATION	1
SHAKING	1
SKIN IRRITATION	1
SWOLLEN LIP	1
TASTE ALTERATION	1
TINGLING SENSATION	1
TINGLING SKIN	1

Species: Human  
Route of Administration: UNKNOWN

<b>Sign :</b>	<b>Number of Times Reported :</b>
BAD TASTE	1
HIVES	1
ITCHING	1
MALAISE	1

**DRUG: FLURALANER**

Species: Tiger  
Route of Administration: TOPICAL

Sign :	Number of Times Reported :
LACK OF EFFICACY (ECTOPARASITES)	1