

## Summary of Product Characteristics

### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Aludex 50 g/l Concentrate for cutaneous solution

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each litre contains:

**Active Substance:**

Amitraz (as Amitraz technical) 50 g

For a full list of excipients see section 6.1

### 3 PHARMACEUTICAL FORM

Concentrate for cutaneous solution.  
Clear pale yellow liquid.

### 4 CLINICAL PARTICULARS

#### 4.1 Target Species

Dogs.

#### 4.2 Indications for use, specifying the target species

For the control of demodectic and sarcoptic mange.

#### 4.3 Contraindications

Do not use on Chihuahuas.

Do not use on dogs suffering from heat stress.

Do not use on pregnant or lactating bitches, nor puppies less than 3 months old.

Do not use on cats.

#### 4.4 Special warnings for each target species

None.

## 4.5 Special precautions for use

### Special precaution(s) for use in animals

For use on dogs only.

For external use only.

For use only under the supervision of a veterinary surgeon.

Dogs should be prevented from licking the fur after treatment.

For the treatment of demodectic mange in severely debilitated dogs use 25 ml of Aludex in 5 litres of water (half the normal dose rate)

### Special precautions to be taken by the person administering the veterinary medicinal product to animals

Flammable. Prepare and use the dilution of the product in a well-ventilated area.

Wear waterproof gloves, apron and face shield when handling the product and wash all protective clothing thoroughly after use, including the inside of gloves.

May cause sensitisation (allergy) by skin contact. Avoid any contact of the product with the skin or eyes. In case of skin contamination, wash thoroughly with soap and water. In case of eye contamination, rinse with plenty of clean, running water immediately. If irritation persists, seek medical help.

Do not eat drink or smoke whilst using the product.

When treatment is completed, wash hands thoroughly before eating, drinking or smoking.

Do not handle treated animals without use of protective clothing until the treatment has dried thoroughly. Treated animals should not be allowed to sleep or play with people, particularly children, until the animal is dry.

If you feel unwell, seek medical advice taking the product leaflet with you.

*To the physician:*

Amitraz is NOT an organophosphorous compound.

Do NOT use atropine as an antidote.

Do NOT induce vomiting.

Treatment should be symptomatic and supportive, paying particular attention to monitoring of respiratory and cardiac function. Recovery, however, is normally spontaneous.

## 4.6 Adverse reactions (frequency and seriousness)

Aludex treatment can lead to known side-effects in a small number of dogs.

In rare cases neurological disorders (ataxia, lethargy, sedation and CNS depression), skin reactions (erythema, pruritus and dermatitis), digestive tract disorders (diarrhoea and emesis), salivation, anorexia, shallow breathing, dyspnoea, bradypnoea, bradycardia, and allergic reactions (oedema) could be observed.

Most of these signs are due to alpha-2-adrenoreceptor agonistic effects. Signs are usually transitory and generally resolved without treatment. If symptoms persist, the dog should be washed in soapy water (not washing-up detergent), dried and warmed. The alpha-2-adrenoreceptor antagonist, atipamezole hydrochloride, may be used at a dose of 0.2 mg/kg body weight by intramuscular injection to reverse these side-effects.

## 4.7 Use during pregnancy, lactation or lay

Contra-indicated in the absence of adequate safety trials data.

## 4.8 Interaction with other medicinal products and other forms of interaction

This product can be used with other dermatological preparations, except those that are water-repellent, and with anthelmintics.

Concurrent use with other alpha-2-adrenoreceptor agonists is not recommended.

Do not use simultaneously with other ectoparasiticide preparations.

## 4.9 Amounts to be administered and administration route

For external topical use only.

Shake the container/ bottle before use.

Make up wash immediately before use.

### Dosage:

#### **Demodectic mange:**

Use 50 ml Aludex concentrate per 5 litres of water (or 100 ml per 10 litres of water for large dogs). Whatever quantity of wash is required it is essential that the initial concentration is not varied from 1 part Aludex to 100 parts water (0.05 % w/v amitraz).

Repeat the treatment at intervals of 5-7 days until neither live mites nor viable eggs can be identified microscopically by skin scrapings. Alternatively, continue treatment for at least 3 weeks after all overt clinical symptoms have subsided

#### **Sarcoptic mange:**

Use 25 ml Aludex per 5 litres of water (or 50 ml per 10 litres water for large dogs). Do not vary the concentration from 1 part Aludex to 200 parts water. (0.025 % w/v amitraz).

Repeat treatment at weekly intervals for 2 to 6 weeks.

### Application method:

1. If necessary, shampoo the dog to remove dirt and grease. Long-haired animals can be clipped prior to treatment if required.
2. Prepare the dog wash outdoors or in a very well ventilated area by adding the appropriate amount of Aludex concentrate to the required volume of clean warm water, stirring to ensure complete mixing. Prepare only the required amount of wash for the individual treatment. Diluted, fouled wash becomes unstable after 6 hours and must be safely discarded. Note that sufficient wash should be prepared to allow complete immersion of the dog's paws and to enable complete wetting of the animal. 5 litres of the diluted wash is normally a minimum requirement and up to 10 litres may be required for larger dogs.
3. In the well ventilated area, stand the dog in a suitable bath or sink and pour the diluted Aludex wash over the animal, gently working into the skin and hair with a soft brush or sponge to ensure that the dog is thoroughly wetted to the skin in all areas. Avoid excessive contact with mucosal membranes.
4. DO NOT rinse the dog, but remove it from the bath and allow it to dry naturally in a warm draught-free place. Alternatively, it can be a good idea to take the dog for a short walk after treatment to allow it to start to dry. This also helps to disperse the solvent fumes and stops the dog licking itself and ingesting the wash. Using an Elizabethan collar to prevent licking can also be helpful on some dogs.
5. Avoid handling the dog after treatment until the coat is dry.

## 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Even after accidental overdose, adverse effects should not exceed those described under 4.6.

Refer to this section for recommended actions.

Clinical signs of toxicity include:

- i) Signs of CNS depression e.g. drowsiness.
- ii) Reduced body temperature.
- iii) Reduced heart rate and blood pressure.
- iv) Increased blood sugar levels (alpha-2-adrenergic agonists are known to reduce insulin release, e.g. clonidine)
- v) Delayed gastro-intestinal transit

## 4.11 Withdrawal Period(s)

Not applicable.

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, amitraz.

ATCvet code: QP53AD01

### 5.1 Pharmacodynamic properties

#### Acute toxicity (single dose studies)

##### A) Technical material, amitraz

<u>Species</u>	<u>Sex</u>	<u>Route</u>	<u>LD<sub>50</sub> (mg/kg)</u>
Rat	Male	Oral	650
Rat	Male	Dermal	>1600

##### B) Formulated product – Aludex

<u>Species</u>	<u>Sex</u>	<u>Route</u>	<u>LD<sub>50</sub> (mg/kg)</u>
Rat	Male	Oral	2259
Rat	Male & Female	Dermal	>2100

#### Toxicity with repeat administration

##### Technical material, amitraz

<u>Species*</u>	<u>Route</u>	<u>Duration</u>	<u>No effect level</u>
Rat	Oral	90 days	3 mg/kg/day
Rat	Oral	2 years	2 mg/kg/day

\* males and females in each case

#### Mutagenicity, Teratogenicity and Carcinogenicity

Amitraz was inactive in a wide range of laboratory tests for genotoxicity and mutagenicity and is not teratogenic. There was no evidence of tumourigenesis in the rat carcinogenicity study but in a mouse oncogenicity study there were liver tumours in high dose (dietary level of 400ppm) animals. This was seen in females only, was species specific and of no relevance for humans.

#### Mode of action and clinical symptomology

Amitraz has a variety of pharmacological activities, which are believed to contribute both to its biological efficacy and to the clinical signs of toxicity.

Amitraz is a contact insecticide/acaricide with extended residual activity, functioning as an agonist at octopamine receptors in the nerve synapses. This produces increased nervous activity leading to rapid detachment of parasites and their eventual mortality. This novel mode of action differs from other established insecticides e.g. organophosphates, carbamates and pyrethroids.

In mammals, the following activities have been reported:

- i) Alpha-2-adrenoreceptor agonist:  
This is the main activity responsible for most clinical signs.
- ii) Weak inhibitor of serotonin receptors
- iii) Weak H<sub>1</sub> receptor antagonist.
- iv) Mono-amine oxidase inhibitor *in vitro* but not apparently *in vivo*.

## 5.2 Pharmacokinetic properties

Dermal absorption of amitraz is relatively slow and achieves peak blood levels 24-72 hours after dosing. Less than 40% of the total applied dose was absorbed in studies on dogs over a period of 10 days following treatment.

Metabolism appears to follow the same route in all mammals observed to date. Initial hydrolysis is to N-(2,4-dimethylphenyl)-N'-methylformamidine (BTS 27271) and 2,4-dimethylformanilide (BTS 27919). The main end products of metabolism are excreted predominantly in the urine and consist of 2-methyl-4-carboxyformanilide (BTS 39098), 4-acetamido-3-methylbenzoic acid (FBC 31158), their respective conjugates and conjugates of 4-amino-3-methylbenzoic acid (BTS 28369). All these products may be converted to BTS 28369 by acid hydrolysis during extraction and processing. Excretion has been rapid following oral dosing in all species studied, with urine as the major route, accounting for 65-84 % of the dose (55-76 % in the first 24 hours).

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Tetraisopropylidiphenylcarbodiimide (Stabaxol 1)  
Nonyl phenol-ethylene oxide condensate (Ethylan KEO)  
Naphtha 21/99

### 6.2 Incompatibilities

None known.

### 6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.  
Dispose of diluted solution immediately after use.

### 6.4 Special precautions for storage

Do not store above 25°C.  
Store in tightly closed original container in safe place.  
Store away from food, drink and animal feeding stuffs.  
Store in a dry place.

### 6.5 Nature and composition of immediate packaging

50 ml of concentrate in a 60 ml Type III amber glass bottle with a white polypropylene/polyethylene (PP/PE) child-proof screw cap with expanded low density PE/aluminium foil/ PE faced wad.

### 6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Harmful to fish and other aquatic life. Do not contaminate ponds, waterways and ditches with concentrate, the diluted wash or used containers.  
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.  
Unused diluted wash can be discarded through the normal waste disposal system.

**7 MARKETING AUTHORISATION HOLDER**

Intervet Ireland Ltd.  
Magna Drive  
Magna Business Park  
Citywest Road  
Dublin 24

**8 MARKETING AUTHORISATION NUMBER(S)**

VPA: 10996/101/001

**9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

30<sup>th</sup> September 2009

**10 DATE OF REVISION OF THE TEXT**

November 2014