PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON: 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aludex 50 g/l Concentrate for cutaneous solution
Amitraz

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains 50 g/l Amitraz (as Amitraz technical).

3. PHARMACEUTICAL FORM

Concentrate for cutaneous solution.

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

Dogs. <pictogram of dog>

6. INDICATION(S)

Indications, Dosage and Administration, Warnings and Disposal Advice:
Read package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external topical use in dogs.
Shake well before use.
Indications, Dosage and Administration, Warnings and Disposal Advice:
Read package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Indications, Dosage and Administration, Warnings and Disposal Advice:
Read package leaflet before use.

10. EXPIRY DATE

EXP end of:

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Indications, Dosage and Administration, Warnings and Disposal Advice:
Read package leaflet before use.
Dispose of diluted solution immediately after use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

UK only

Vm 01708/4408

POM-V

IE only

VPA 10996/101/001

POM

MA Holder in the UK:
MSD Animal Health
UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

MA Holder in Ireland and distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4408

17. MANUFACTURER'S BATCH NUMBER

Batch:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label 50 ml bottle

<dog pictogram>

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aludex 50 g/l Concentrate for cutaneous solution
Amitraz

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Contains 50g/l Amitraz (as Amitraz technical).

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml

4. ROUTE(S) OF ADMINISTRATION

Concentrate for cutaneous solution.
For external topical use in dogs.

5. WITHDRAWAL PERIOD

Withdrawal period: Not applicable

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

EXP end of
Use immediately after dilution.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

OTHER INFORMATION

Keep out of the sight and reach of children.
For the control of demodectic and sarcoptic mange.
Read package leaflet before use.

To be supplied only on veterinary prescription.

UK: POM-V Vm 01708/4408

IE: POM VPA 10996/101/001

PACKAGE LEAFLET FOR
Aludex 50 g/l Concentrate for cutaneous solution

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

UK only

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

IE only

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

Manufacturer for the batch release:
Intervet Productions S.A.
Rue de Lyons
27460 Igoville
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aludex 50 g/l Concentrate for cutaneous solution
Amitraz

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Contains 50g/l Amitraz (as Amitraz technical).
Clear pale yellow liquid

4. INDICATION(S)

For the control of demodectic and sarcoptic mange.

5. 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.

6. ADVERSE REACTIONS

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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

See above.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25 °C.
Store in original container tightly closed, in safe place.
Store away from food, drink and animal feeding stuffs.
Store in a dry place.
Do not use after the expiry date stated on the carton or label.
Dispose of diluted solution immediately after use.

12. SPECIAL WARNING(S)

Special precautions 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.

Adverse reactions:
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.

Use during pregnancy and lactation:
Contra-indicated in the absence of adequate safety trials data.

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.

Overdose (symptoms, emergency procedures, antidotes):
Even after accidental overdose, adverse effects should not exceed those described above under ‘Adverse reactions’. 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2021

15. OTHER INFORMATION

For animal treatment only.

Pack size: 50 ml

UK only	**IE only**
Vm 01708/4408	VPA 10996/101/001
POM-V	POM
To be supplied only on veterinary prescription.	Prescription only medicine.

Approved: 09/06/21