PARTICULARS TO APPEAR ON THE OUTER PACKAGE – Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aurimic ear drops and cutaneous suspension for dogs and cats

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Miconazole nitrate 23.0 mg
(equivalent to 19.98 mg miconazole)
Prednisolone acetate 5.0 mg
(equivalent to 4.48 mg prednisolone)
Polymyxin B sulfate 0.5293 mg
(equivalent to 5500 IU polymyxin B sulfate)

3. PACKAGE SIZE

20 ml

4. TARGET SPECIES

Dogs and cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For auricular and cutaneous use. Shake well before use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months. Use by …

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30 °C. After first opening do not store above 25 °C. Keep the container in the outer carton.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

VetViva Richter (logo)

14. MARKETING AUTHORISATION NUMBER

Vm 57446/4004

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS – Squeeze dropper bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aurimic

Dogs, cats

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Miconazole nitrate 23.0 mg/ml
Prednisolone acetate 5.0 mg/ml
Polymyxin B sulfate 0.5293 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use by …

20 ml

Shake well.

VetViva Richter (logo)

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Aurimic ear drops and cutaneous suspension for dogs and cats

2. Composition

Each ml (40 drops) contains:

Active substances:
Miconazole nitrate 23.0 mg
(equivalent to 19.98 mg miconazole)
Prednisolone acetate 5.0 mg
(equivalent to 4.48 mg prednisolone)
Polymyxin B sulfate 0.5293 mg
(equivalent to 5500 IU polymyxin B sulfate)

White suspension.

3. Target species

Dogs and cats.

4. Indications for use

For the treatment of otitis externa and small localised superficial skin infections in dogs and cats caused by infections with the following bacteria and fungi:

- Gram-positive bacteria
  - *Staphylococcus* spp.
  - *Streptococcus* spp.
- Gram-negative bacteria
  - *Pseudomonas* spp.
  - *Escherichia coli*
- Fungi
  - *Malassezia pachydermatis*
  - *Candida* spp.
  - *Microsporum* spp.
  - *Trichophyton* spp.

Treatment of *Otodectes cynotis* (ear mites) infestations where there is concurrent infection with miconazole and polymyxin B sensitive pathogens.

5. Contraindications

Do not use:

- in cases of hypersensitivity to the active substances, as well as to other corticosteroids, to other azole antifungal agents, or to any of the excipients,
- in animals with perforation of the tympanic membrane,
- in animals, where resistance of causative agents to polymyxin B and/or miconazole is known,
- on the mammary glands of lactating bitches and queens.

6. Special warnings

Special warnings:
Bacterial and fungal otitis is often secondary in nature. The underlying cause should be identified and treated.

Special precautions for safe use in the target species:
Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target bacteria and/or fungi isolated from the animal. If this is not possible, therapy should be based on local (regional) epidemiological information and knowledge of susceptibility of the target pathogens.
Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.
An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category)
should be used for first line treatment where susceptibility testing suggests the likely efficacy of
this approach.
In cases of persistent infestations with *Otodectes cynotis* (ear mites) systemic treatment with an appropriate acaricide should be considered.
Before treating with the veterinary medicinal product, the integrity of the tympanic membrane must be verified.
Systemic corticosteroid effects are possible, especially when the veterinary medicinal product is used under an occlusive dressing, on extensive skin lesions, with increased skin blood flow, or if the veterinary medicinal product is ingested by licking.
Oral ingestion of the veterinary medicinal product by treated animals or animals having contact with treated animals should be avoided.
Avoid contact with eyes in animals. In case of accidental contact, rinse thoroughly with water.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to prednisolone, polymyxin B or miconazole should avoid contact with the veterinary medicinal product.
The veterinary medicinal product may cause irritation to skin and eyes. Avoid contact with skin or eyes. Always wear single use disposable gloves when applying the veterinary medicinal product to animals. In case of accidental spillage, skin or eyes should be rinsed immediately with plenty of water. Wash hands after use.
Take care to avoid accidental ingestion. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Absorption of miconazole, polymyxin B and prednisolone through the skin is low, therefore no teratogenic/embryotoxic/foetotoxic and maternotoxic effects are expected in dogs and cats.
Oral ingestion of the active substances by treated animals when grooming can possibly occur and appearance of the active ingredients in blood and milk can be expected.
Use only according to the benefit-risk assessment by the responsible veterinarian.

Overdose:
No other symptoms than those mentioned in section “Adverse events” are expected.

7. Adverse events

Dogs, cats:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):
Deafness[1].

Undetermined frequency (cannot be estimated from the available data):
Other immune system disorders[2,3]; Application site infection[2], Application site bleeding[2,4]; Skin thinning[2]; Delayed healing[2], Systemic disorder[2] (e.g. Adrenal gland disorder[2,5]); Telangiectasia[2] (Dilated skin blood vessels).

[1] Especially in older dogs. In this case treatment should be discontinued.
[2] After prolonged and extensive use of topical corticosteroid preparations.
[3] Local immunosuppression including increased risk of infections.
[4] Increased vulnerability of the skin to bleeding.
[5] Suppression of adrenal function.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or using the contact details at the end of this leaflet, or via your national reporting system:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

For auricular and cutaneous use.

At the beginning of treatment, hair surrounding or covering the lesions must be clipped; this should be repeated during treatment if necessary.

Infections of the external auditory canal (otitis externa):

Clean the external ear canal and auricle and place 5 drops of the veterinary medicinal product into the external auditory canal twice a day. Massage the ear and the auditory canal thoroughly to ensure proper distribution of the active substances, but gently enough to avoid causing pain to the animal.
Treatment should be continued without interruption until a few days after complete disappearance of the clinical symptoms, at least for 7 - 10 days up to 14 days. The success of the treatment should be verified by a veterinarian before discontinuing treatment.

Skin infections (small localised superficial):
Apply a few drops of the veterinary medicinal product to the skin lesions to be treated twice a day and rub well.
Treatment should be continued without interruption until a few days after complete disappearance of the clinical symptoms, up to 14 days.

In some persistent cases (ear or skin infections), treatment may need to be continued for 2 to 3 weeks. However, if prolonged treatment is necessary, the veterinarian should be contacted for a repeat clinical examination.

9. Advice on correct administration

Shake well before use. Any contamination of the dropper should be strictly avoided.
See also section “Special warnings”.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 30 °C. After first opening do not store above 25 °C.
Keep the container in the outer carton.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and bottle label after “Exp.”. The expiry date refers to the last day of that month.
Shelf-life after first opening the immediate packaging: 3 months

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 57446/4004

Pack size: 1 x 20 ml

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:

VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria
Tel: +43 (0)664 8455326
E-mail: adverse.events@vetviva.com

17. Other information

POM-V

Gavin Hall

Approved 27 February 2025