aurimic®

Aurimic® Ear Drops and Cutaneous Suspension for Dogs and Cats

Miconazole nitrate, Prednisolone acetate, Polymyxin B sulfate

Statement of the active substances and other ingredients

Each ml contains:

Active substances:

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

White suspension.

Indications

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

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

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

Contraindications

Do not use:

- in cases of hypersensitivity to the active substances of the veterinary medicinal product, as well as to other corticosteroids, to other azole antifungal agents, or to the excipients
- in animals with perforated ear drums
- in animals, where resistance of causative agents to polymyxin B and/or miconazole is known
- on the mammary glands of lactating bitches and queens

Adverse reactions

Use of this veterinary medicinal product may very rarely be associated with the occurrence of deafness (especially in older dogs), in this case treatment should be discontinued.

Prolonged and extensive use of topical corticosteroid preparations is known to trigger local and systemic effects, including suppression of adrenal function, thinning of the epidermis and delayed healing.

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

Target species

Dogs and cats.

Dosage for each species, routes and method of administration

For auricular and cutaneous use. Shake well before 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.

Where concurrent ear mite (*Otodectes cynotis*) infestation is present, consideration should be given to treating both ears even if infestation is only apparent in one ear. Instill 5 drops twice daily for 14 days.

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.

Advice on correct administration

Shake well before use.
See Special warnings section.

Withdrawal period

Not applicable.

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.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and bottle label after "EXP".
Shelf-life after first opening the container: 3 months.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified, the date on which any product remaining should be discarded should be worked out. This discard date should be written in the space provided.

Special warnings

Special precautions for use in animals
Use of the product should be based on microbiological sampling and susceptibility testing of the bacteria and/or fungi isolated from the animal. If this is not possible, therapy should be based upon local (regional) epidemiological information about susceptibility of the causative pathogens.
Systemic corticosteroid effects are possible, especially when the product is used under an occlusive dressing, on extensive skin lesions, with increased skin blood flow, or if the product is ingested by licking.
Oral ingestion of the product by treated animals or animals having contact with treated animals should be avoided.

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.
Avoid contact with skin or eyes. In case of accidental spillage, skin or eyes should be rinsed immediately with plenty of water. Always wear single use disposable gloves when applying the veterinary medicinal product to animals. Wash hands after use.
In case of accidental ingestion, seek medical advice immediately and show the leaflet or the label to the physician.

Use during pregnancy and lactation:
The safety of the product has not been assessed during pregnancy and lactation.
Use only accordingly to the benefit/risk assessment by the veterinarian.

Special precautions for the disposal of unused product or waste materials, if any

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Date on which the package leaflet was last approved: June 2016

Other information

Pack size: 1 x 20ml
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.
To be supplied only on veterinary prescription.
For animal treatment only.

Marketing Authorisation Holder:
Richter Pharma AG,
Feldgasse 19, 4600 Wels, Austria

Manufacturer responsible for batch release:
Richter Pharma AG,
Durisolstrasse 14, 4600 Wels, Austria

Distributed by:
Animalcare Ltd,
10 Great North Way, York
YO26 6RB, UK

UK only:	**IE only:**
Vm 22080/4006 POM-V	VPA 10801/007/001 POM Prescription Only Medicine.

60488/A