ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

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. PHARMACEUTICAL FORM

Ear drops and cutaneous suspension

4. PACKAGE SIZE

20 ml

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

-

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Auricular and cutaneous use. Shake well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

-

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {day/month/year}
Shelf-life after first opening the container: 3 months. Once opened, use by ...

11. SPECIAL STORAGE CONDITIONS

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

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

Disposal: read package leaflet.

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

VetViva Richter GmbH
Durisolstrasse 14
4600 Wels
Austria

16. MARKETING AUTHORISATION NUMBER(S)

Vm 57446/4004

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Squeeze dropper bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aurimic ear drops and cutaneous suspension for dogs and cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

20 ml

4. ROUTE(S) OF ADMINISTRATION

Auricular and cutaneous use. Shake well.

5. WITHDRAWAL PERIOD(S)

-

6. BATCH NUMBER

Lot: {number}

7. EXPIRY DATE

EXP: {day/month/year}
Once opened, use by …

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Aurimic ear drops and cutaneous suspension for dogs and cats

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

Marketing authorisation holder:
VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aurimic ear drops and cutaneous suspension for dogs and cats

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

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.

4. INDICATION(S)

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*
- 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 of the veterinary medicinal product, 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. 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 immunosuppression including increased risk of infections, thinning of the epidermis and delayed wound healing, telangiectasia and increased vulnerability of the skin to bleeding and systemic effects, including suppression of adrenal function.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon. Alternatively you can report via your national reporting system.

7. TARGET SPECIES

Dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 special warnings section.

10. WITHDRAWAL PERIOD(S)

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”.
Shelf-life after first opening the container: 3 months

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Use of the product should be based on susceptibility testing of the bacteria and/or fungi isolated from the animal. If this is not possible, therapy should be based on local (regional) epidemiological information about susceptibility of the target pathogens.
In cases of persistent infestations with *Otodectes cynotis* (ear mites) systemic treatment with an appropriate acaricide should be considered.
Before treating with the product, the integrity of the tympanic membrane must be verified.
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.
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 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. Use only in accordance with the benefit/risk assessment by the responsible veterinarian.

13. 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.

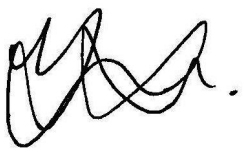
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2023

15. OTHER INFORMATION

Pack size: 1 x 20 ml

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.



Approved: 23 January 2023