SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aurimic ear drops and cutaneous suspension for dogs and cats

2. QUALITATIVE AND QUANTITATIVE 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)

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ear drops and cutaneous suspension
White suspension

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats

4.2 Indications for use, specifying the target species

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.

4.3 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

4.4 Special warnings for each target species

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

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

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 being low, 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 in accordance with the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

No data available.

4.9 Amounts to be administered and administration route

For auricular and cutaneous use.
Shake well before use. Any contamination of the dropper should be strictly avoided.

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. In cases where prolonged treatment is necessary repeated clinical examinations including a re- assessment of the diagnosis are required.

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

No other symptoms than those mentioned in section 4.6 are expected.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Otologicals, corticosteroids and antiinfectives in combination.
ATCvet code: QS02CA01

5.1 Pharmacodynamic properties

Miconazole belongs to the group of N-substituted imidazole derivatives and inhibits ergosterol *de novo* synthesis. Ergosterol is an essential membrane lipid and must be synthesised by fungi. Ergosterol deficiency impedes numerous membrane functions, eventually leading to the cell's death. The spectrum of activities covers nearly all fungi and yeasts of relevance to veterinary medicine as well as Gram-positive

bacteria. Practically no development of resistance has been reported. Miconazole has a fungistatic mode of action, but high concentrations are also observed to produce fungicidal effects.

Polymyxin B belongs to the polypeptide antibiotics which are isolated from bacteria. It is only active against Gram-negative bacteria. The development of resistance is chromosomal in nature and the development of resistant Gram-negative pathogens is a relatively rare event. However, all *Proteus* species share a natural resistance to polymyxin B.
Polymyxin B binds to phospholipids in the cytoplasmic membrane to disturb membrane permeability. This results in autolysis of the bacteria, thus achieving bactericidal activity.

Prednisolone is a synthetic corticosteroid and is used for its anti-inflammatory, anti-pruritic, anti- exudative and anti-proliferative effects. The anti-inflammatory activity of prednisolone acetate results from reduction of the permeability of capillaries, improved blood flow and inhibition of fibroblast action.

The exact mechanism of the acaricidal effect is unclear. It is assumed that the mites are suffocated or immobilised by the oily excipients.

5.2 Pharmacokinetic particulars

Following topical application of polymyxin B, there is virtually no absorption of the compound through intact skin and mucous membranes, but significant absorption via wounds.

After topical application of miconazole, there is virtually no absorption of the compound through intact skin or mucous membranes.

When applied topically to intact skin, prednisolone is subject to limited and delayed absorption. Greater absorption of prednisolone should be expected in cases of compromised skin barrier function (e.g. skin lesions).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Silica, colloidal anhydrous
Paraffin liquid

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 3 months

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Dropper container of white, opaque LDPE with white, opaque HDPE screw cap in a cardboard box.

Pack size: 1 x 20 ml

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Richter Pharma AG
Feldgasse 19
4600 Wels
Austria

8. MARKETING AUTHORISATION NUMBER

Vm 22080/4006

9. DATE OF FIRST AUTHORISATION

05 March 2015

10. DATE OF REVISION OF THE TEXT

November 2019

Approved: 12 November 2019