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 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*
- 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.

4.3 Contraindications

Do not use:
- in case 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

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 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 target 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.

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 and systemic effects, including suppression of adrenal function, thinning of the epidermis and delayed healing.

4.7 Use during pregnancy and lactation

The safety of the product has not been assessed 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 accordingly to the benefit/risk assessment by the 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.

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. 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 anti-infectives 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 Incompatibilities

None known.

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.

6.5 Nature and composition of immediate packaging

Dropper container of white, opaque LDPE with white, opaque HDPE screw cap. 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
Austria

8. MARKETING AUTHORISATION NUMBER

Vm 22080/4006

9. DATE OF FIRST AUTHORISATION

05 March 2015

10. DATE OF REVISION OF THE TEXT

July 2015

DISTRIBUTED BY
Animalcare Ltd
10 Great North Way
York Business Park
Nether Poppleton
York
YO26 6RB

APPROVED T. NASH **23/07/15**