

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Chanear Ear Drops and Cutaneous Suspension for Cats and Dogs

### 2. Composition

Each ml of white to off white suspension 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	5500 IU

### 3. Product description

White to off-white ear drops, suspension.

### 4. Indications for use

For the topical treatment of otitis externa and skin infections caused by Gram-positive bacteria e.g. *Staphylococcus aureus*, *Streptococcus spp.*, and Gram-negative bacteria *Escherichia coli* and *Pseudomonas aeruginosa*.

For the topical treatment of otitis externa and skin infections caused by fungi and yeasts: *Trichophyton spp.*, *Microsporium spp.*, *Malassezia pachydermatis*, *Candida spp.*

For the topical treatment of otitis externa caused by the ear mite *Otodectes cynotis* and complicated by microorganisms sensitive to miconazole and polymyxin B.

The product also has anti-inflammatory and anti-pruritic activity.

### 5. Pharmacodynamics

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 resistance 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 acetate is a glucocorticoids with strong anti-inflammatory activity which results from its reduction of the permeability of capillaries and vascular proliferation and from the inhibition of fibroblast action.

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

### 6. Pharmacokinetics

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).

### 7. Dosage, Routes and Method of administration

For auricular and cutaneous use.

Routes of administration: For instillation in the external auditory canal or for cutaneous application.

Shake the bottle vigorously and ensure the product is fully resuspended before use.

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

Ears: Clean the auditory canal and place a few drops of the product into the ear twice daily.

For infections caused by *Otodectes cynotis*, instil five drops twice daily for 14 days.

Massage the ear and the auditory canal gently but thoroughly to ensure proper distribution.

The success of the treatment should be verified by a veterinarian before discontinuing treatment.

Skin: Having ensured the area to be treated is clean, apply a few drops of the product (depending on lesion size) twice a day and rub well.

Treatment should be continued until a few days after complete disappearance of the clinical symptoms. In some obstinate cases, treatment may be required for 2 to 3 weeks. In cases where prolonged treatment is necessary repeated clinical examinations including a re-assessment of the diagnosis are required.

Where ear mite infection is present, consideration should be given to treating both ears even if infestation is only apparent in one ear.

### 8. Contraindications

Do not use:

- in cases of hypersensitivity to the active substances of the veterinary medicinal products, as well as to other corticosteroids, to otherazole antifungal agents, or to any of the excipients
- in cases of skin viral infections
- in cases of large skin lesions and of poorly healing or fresh wounds
- 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

### 9. 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 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.

## 10. Adverse events

Target species: Cats and dogs

Very rare (<1 animal / 10,000 animals treated, including isolated reports)	Deafness*
Undetermined frequency	Infection, skin thinning, delayed healing, application site bleeding; adrenal gland disorder

\*Especially in older dogs, discontinue treatment if deafness occurs.

Prolonged and extensive use of topical corticosteroid preparations is known to lead to local immunosuppression (resulting in the specific local effects detailed in the table, also including telangiectasia), and systemic effects, including suppression of adrenal function.

## 11. Special warnings

Bacterial and fungal otitis is often secondary in nature. The underlying cause should be identified and treated. Cross-resistance has been shown between polymyxin B and colistin in *E.coli*. Use of the product should be carefully considered when susceptibility testing has shown resistance to polymyxins because its effectiveness may be reduced.

## 12. Special precautions for use

Special precautions for safe use in the target species:

For external use only. Use of the product should be based on identification and susceptibility testing of the target pathogens. If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at local/regional level.

Use of the 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. This antimicrobial combination should only be used where diagnostic testing has indicated the need for simultaneous administration of each of the active substances.

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 occlusive dressing, 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 animal:

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.

Special precautions for the disposal:

Medicines should not be disposed of via wastewater or household waste. 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 national collection systems applicable to the veterinary medicinal product concerned.

## 13. Interaction with other medicaments

No data available.

## 14. Symptoms of overdose

No other symptoms than those mentioned in adverse effects are expected.

## 15. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25°C. Keep the container in the outer carton in order to protect from light.

Do not refrigerate or freeze.

Once opened use within three months. Discard unused material.

## 16. Pack sizes

15 ml dropper bottle.

Controlled Medicines/ Ubat Terkawal.

FOR VETERINARY USE ONLY.

## 17. Manufactured by:

Chanelle Pharmaceuticals Manufacturing Ltd,  
Ida Industrial Estate, Dublin Road, Loughrea, H62 FH90, Ireland.

## 18. Registration Holder:

Rhone Ma Malaysia Sdn Bhd (200001023279),  
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