



Mitex



**PARTICULARS TO APPEAR ON THE PACKAGE
LEAFLET:**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Mitex ear drops and cutaneous suspension

2. COMPOSITION	
Active substances	mg/ml
Miconazole Nitrate	23
Prednisolone Acetate	5
Polymyxin B Sulfate	0.5293
Excipients: Silica colloidal anhydrous, liquid paraffin.	

White suspension.

3. TARGET SPECIES
Cats and dogs.

4. INDICATIONS FOR USE
For the topical treatment of otitis externa and skin infections caused by Gram-positive bacteria e.g. *Staphylococcus aureus* and *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.*, *Microsporum spp.*, *Malassezia pachydermatis*, *Candida spp.*
For the topical treatment of otitis externa caused by the ear mite *Otodectes cynotis*.
The product also has anti-inflammatory and anti-pruritic activity.

5. CONTRAINDICATIONS
Do not use in animals with perforated ear drums since Polymyxin B is known to be a potential ototoxic agent.
Do not use in cases of known hypersensitivity to the active substances or to any of the excipients.

6. SPECIAL WARNING(S)
As the veterinary medicinal product is a prescription only medicine, treatment should be closely supervised by a veterinary practitioner.

Special precautions for safe use in the target species:
For external use only.
Due to the likely variability (temporal, geographical) in the

emergence of bacterial resistance to Polymyxin B, bacteriological sampling and sensitivity testing (antibiogram) is recommended.
If there is overgrowth of resistance bacteria and/or fungi, treatment with this veterinary medicinal product should be discontinued and treatment with an appropriate alternative should be initiated.

Pregnancy:
Corticosteroids are not recommended for use in pregnant animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Do not handle the product if you are allergic to the ingredients in the product.
Accidental spillage on the skin should be washed off immediately with soap and water. Wash hands after use. Corticosteroids may produce irreversible effects in the skin. They can be absorbed and may have harmful effects, especially with frequent and extensive contact or when used in pregnancy. Always wear single use disposable gloves when applying the veterinary medicinal product to animals.

Interactions with other medicinal products and other forms of interaction:
Do not use concomitantly with medicines that induce ototoxicity.

Overdose:
Topical use. In case of accidental ingestion by licking, no toxic effects were observed.

Major incompatibilities: None known.

7. ADVERSE EVENTS
Dogs and cats:
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Deafness¹; impaired hearing¹.

¹ Mainly in elderly dogs. If this occurs, treatment should be stopped. Decreased hearing or deafness is generally temporary in nature.

Prolonged use of topical steroids can cause skin discoloration and delay wound healing.

The conventional adverse effects of corticosteroids can occur (disturbance of biochemical parameters, such as increased cortisol and hepatic enzyme levels).

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.



DATE OF REVISION: 01/07/2026



Design Information	
Size	148 x 210 mm (DIN A5)
Text column 1	9 pt
Text column 2	9 pt
Packaging No.	00000/A
Font type	Myriad Pro, Akzidenz-Grotesk Pro
Colours used	Pantone Black 6 C ■
PDF Version	1.6
Approval date + signature	



8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

This veterinary medicinal product is for topical administration. 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*, instill five drops twice daily for 14 days. Massage the ear and the auditory canal gently but thoroughly to ensure proper distribution.

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 (see also 4.6).

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

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD(S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children. Do not store above 25 °C.

Keep the dropper bottle in the outer carton. Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: three months. When the container is breached (opened) for the first time, using the in-use shelf life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

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

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

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13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Registration No.: MAL XXXX

Pack size: 1 x 20 ml

15. PHARMACODYNAMIC PROPERTIES:

Miconazole nitrate is a synthetic imidazole derivative with a pronounced antifungal activity and a potent activity against Gram-positive bacteria. Miconazole selectively inhibits the synthesis of ergosterol, which is an essential component of the membrane of yeasts and fungi.

Polymyxin B sulfate is a polypeptide antibiotic with bactericidal activity against Gram-negative bacteria. It binds to phospholipids in the cytoplasmic membrane, whereby the membrane permeability is disturbed. This results in lysis of the bacteria.

Prednisolone acetate is a glucocorticoid 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.

16. PHARMACOKINETICS PROPERTIES:

After topical application of miconazole nitrate, virtually no systemic absorption takes place through the skin or mucus membranes.

Systemic absorption of prednisolone on normal or abraded skin is minimal.

Absorption of polymyxin B via the skin is also negligible. Excretion is almost completely via the kidneys.

17. CONTACT DETAILS

Manufacturer:

VetViva Richter GmbH
Durisolstrasse 14
4600 Wels Austria.

Local representative and contact details to report suspected adverse events/ Product Registration Holder:

Gladron Chemicals Sdn Bhd
No. 7, Jalan TP7, UEP Industrial Park,
40400 Shah Alam, Selangor, Malaysia.

16. OTHER INFORMATION Properties

Miconazole is a synthetic imidazole derivative with a pronounced anti-fungal effect and a potent activity against Gram-positive bacteria. Poly-myxin B is an antibiotic with a bactericidal effect against Gram-negative bacteria. To these two substances, prednisolone has been added to provide anti-inflammatory and antipruritic activities.

KEEP OUT OF REACH OF CHILDREN
FOR ANIMAL USE ONLY
CONTROLLED MEDICINE ONLY

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