

## **Consumer leaflet for a Veterinary Product**

This medicine is marketed according to a veterinarian's prescription only.

For animal use only

### **1. Name of the veterinary medicine, form and strength**

#### **Mitex Veterinary**

Suspension for otic or dermal use

### **2. Active ingredients and quantity per unit dose**

Each mL contains:

Miconazole nitrate 23 mg

Polymyxin B sulfate 0.5293 mg (5500 IU)

Prednisolone acetate 5 mg

For the list of inactive excipients, see section 13 "Additional information".

### **3. What is the medicine intended for**

For the treatment of inflammation of the external ear and cutaneous inflammations of cats and dogs caused by fungi, yeasts and Gram-negative and Gram-positive bacteria sensitive to the drug. Inflammation of the ear caused by Ear mites.

#### **Therapeutic group:**

Miconazole nitrate: Antifungal substance of the imidazole family

Prednisolone acetate: Synthetic corticosteroid

Polymyxin B sulfate: Antibiotic

### **4. Contraindications**

Do not use in animals if the eardrum is damaged, Polymyxin B can cause hearing problems.

Do not use in cases of known hypersensitivity to the active ingredients listed above or to any of the excipients included in the product as detailed in section 13.

### **5. Side effects**

Dogs and cats:

Very rare (occur in less than 1 in 10,000 treated animals, including isolated reports)

- Deafness<sup>1</sup>

- Impaired hearing<sup>1</sup>

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

Prolonged use of topically administered 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).

Side effects can be reported to the Ministry of Health by clicking on the link "Side Effects Report" that appears on the home page of the Ministry of Health web site ([www.health.gov.il](http://www.health.gov.il)), which leads to an online form for reporting side effects. Alternatively, you can use the following link: <https://sideeffects.health.gov.il>

## **6. Target species**

Cats and dogs

## **7. Dosage and administration**

For external use only. This product is intended for topical administration only.

At the beginning of treatment, the hair surrounding or covering the area intended for treatment must be cut and this action should be repeated as needed during further treatment.

**Treatment of inflammation of the external ear** – clean the auditory canal and drip several Mitex drops into the ear twice daily.

For the treatment of ear inflammation caused by mites, it is recommended to drip 5 drops into each ear twice daily for 14 days. The ear and the auditory canal must be gently but thoroughly massaged in order to attain optimal spread of the product in the ear.

**For the treatment of skin inflammation** – make sure that the area intended for treatment is clean. Drip several drops of Mitex (according to the size of the lesion) twice daily. Rub-in thoroughly. The treatment should be continued for several days after the inflammation signs have disappeared. In severe cases, the treatment may be required for two to three weeks.

In mite infections, treating both ears should be considered, even if the infection is apparent in one ear only.

## **8. How to use the product**

Shake the bottle well and ensure the product is fully suspended before use.

## **9. Withdrawal period**

Not applicable

## 10. Warnings

### Special warnings regarding use of the medicine during the treatment of the target species.

The product is intended for external use only.

Due to the existing variability (temporal and geographical) of bacterial resistance to Polymyxin B, it is recommended to perform bacteriological samplings and sensitivity tests.

If there is overgrowth of resistance bacteria and/or fungi, treatment with this product should be discontinued and treatment with an appropriate alternative should be initiated.

### Special warnings regarding the safe use of the medicine in animals

Mitex is a prescription medicine, and its use must be supervised by a veterinarian.

### Special warnings regarding the safety for the person administering the veterinary medicinal product to animals

Do not handle the medicine if you are allergic to one of its components. In the event that the medicine spills on human skin, immediately wash it off thoroughly with water and soap. Wash hands after use.

Corticosteroids can cause irreversible effects in the skin. They may be absorbed and lead to harmful effects, especially with frequent and extensive contact or in pregnant women. **While treating animals, wear protective disposable gloves at all times.**

- Pregnancy and lactation of the treated animal  
Corticosteroids are not recommended for use in pregnant animals.
- Interactions with other medicinal products and other forms of interactions  
Do not use concomitantly with medicines that induce ototoxicity.
- Overdose  
For external (topical) use. In case of accidental ingestion by licking, no toxic effects were observed.

## 11. Storage instructions

- Avoid poisoning! This medicine, and any other medicine, must be kept in a closed place out of the reach and sight of children and/or infants to prevent accidental poisoning.
- Do not use the medicine after expiration date (exp. date) as appears on the package. The expiration date refers to the last day of the stated month.
- Storage conditions- Do not store above 30°C.
- Shelf life after first opening - 3 months, below 25°C.

## **12. Instructions for disposing of the product / remaining product at the end of its use**

Any remaining of the veterinary product or any waste resulting from the use of the veterinary product must be disposed of as toxic waste. Do not dispose of into sewage.

## **13. Additional information**

- In addition to the active ingredients, the medicine also contains:  
Silica colloidal anhydrous, Paraffin liquid
- How does the medicine look like and what is the content of the package:  
The medicine is a liquid suspension in a white plastic bottle equipped with a dropper on its top.
- Package size: 20 mL
- Registration holder: Vetmarket Ltd, 23 Hachosh Way, Industrial Park Modi'in Region 7319900, Israel.
- Manufacturer: VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria

Revised in September 2023 according to MOH's guidelines.

Registration number of the product in the National Drug Registry at the Ministry of Health: 163-71-35449-00