

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

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

For animal use only

### **1. Name of medicine**

**Mitex Veterinary**

Suspension drops

### **2. Active ingredients**

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.

### **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 bacteria sensitive to the drug. Inflammation of the ear caused by *Otodectes cynotis* mites.

#### **Therapeutic group:**

Miconazole nitrate: Anti-fungal substance of the imidazole family

Prednisolone acetate: Synthetic corticosteroid

Polymyxin B sulfate: Antibiotic

### **4. Contraindications**

Must not be used if the eardrum is damaged. Polymyxin B can cause hearing and balance problems.

Hypersensitivity to the active ingredients listed above or to the excipients included in the product as detailed in section 13.

### **5. Side effects**

Prolonged use of locally administered steroids can lead to thinning of the skin and impaired wound healing.

If you notice a severe adverse event or another reaction not mentioned in the leaflet, please notify the veterinarian.

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 local treatment 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.

**Inflammatory treatment 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 mildly 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 take two or three weeks.

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

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

Shake the bottle well before use.

## **9. Withdrawal period**

Not applicable

## **10. Warnings**

### Special warnings regarding use of the medicine in the target species

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

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

- Corticosteroids are not recommended for use in pregnant 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

In the event that the medicine spills on human skin, flush thoroughly with water and soap. Wash hands after use.

Corticosteroids can cause irreversible skin symptoms. They may be absorbed and lead to damaging side effects, in particular if the contact is extensive, occurs frequently or affects pregnant women. **While treating animals, wear protective disposable gloves at all times.**

Do not use the medicine if you are allergic to one of its components.

## **11. Storage instructions**

Avoid poisoning! This medicine, and any other medicine, must be kept in a closed place out of the reach of children and/or infants to prevent accidental poisoning.

Do not use the medicine after its expiration date (exp. date) as it 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:

### **Liquid paraffin, Colloidal anhydrous silica**

The medicine is a liquid suspension in a white plastic bottle equipped with a pipette on its top.

Package size: 20 mL

**Manufacturer:** Richter Pharma AG, Durisolstrasse 14, 4600 Wels, Austria

License holder: Vetmarket Ltd, 23 Hachosh Way, Industrial Park Modi'in Region  
7319900

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

Revised in June 2020.

This leaflet of 06.2020 is in the format determined by the Ministry of Health and its  
content corresponds to the leaflet of the reference product, which was checked and  
approved by the Ministry of Health in 03.2020.