

## CONSUMER PACKAGE INSERT FOR VETERINARY MEDICINAL PRODUCT

The medicine is dispensed with a veterinarian's prescription only

For animal use only

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT:

Surolan Veterinary

Suspension drops

### 2. ACTIVE INGREDIENTS:

Each 1 ml contains:

Miconazole nitrate 23mg

Prednisolone acetate 5mg

Polymixin B sulfate 0.5293mg (5500I.U.)

### 3. WHAT IS THE MEDICINAL PRODUCT INTENDED FOR:

Surolan is used in dogs and cats for the treatment of otitis and skin infections caused by fungi, yeast, gram-negative and gram-positive bacteria, ear mites (*Otodectes cynotis*).

#### Therapeutic group:

Miconazole nitrate: Antifungal from the Imidazole family

Prednisolone acetate: Synthetic corticosteroid

Polymixin B sulfate: Antibiotics

### 4. CONTRAINDICATIONS

Not to be used in animals with perforated ear drums since Polymyxin B may cause hearing and balance problems.

Hypersensitivity to the active ingredient or to one of the other ingredients.

### 5. SIDE EFFECTS

Long-term use of topical steroids may cause skin thinning and delay wound healing.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects due to Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

### 6. TARGET SPECIES

Cats and dogs

### 7. DOSAGE AND ROUTE OF ADMINISTRATION

For external use only.

This product is for topical administration.

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 Surolan into the ear twice a day.

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 obtain optimum distribution of the product.

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

Do not discontinue the treatment until a few days after complete disappearance of the clinical symptoms.

In some obstinate cases, 2 to 3 weeks treatment may be necessary.

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

## 8. METHOD OF ADMINISTRATION

Shake the bottle vigorously before use.

## 9. WITHDRAWAL PERIOD

Not applicable.

## 10. WARNINGS

Special warning concerning the use of the medicine in the target species:

Due to likely variability (time, geographical) in the occurrence of resistance of bacteria for Polymyxin B, bacteriological sampling and susceptibility testing are recommended.

Special warning concerning the use of the medicine in animals:

Corticosteroids are not recommended for use in pregnant animals. As Surolan is a prescription only medicine, treatment should be closely supervised by a veterinary practitioner.

Operator warnings:

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 product to animals.** Do not handle the product if you are allergic to any of the ingredients in the product.

## **11. STORAGE INSTRUCTIONS**

Avoid poisoning! This medicinal product and any other medicinal products, should be kept in a closed place, out of the reach and sight of children and/or infants in order to protect from poisoning.

Do not use the medicinal product after the expiry date (exp. Date) appearing on the package. The expiry date refers to the last day of that month.

Shelf life after first opening: 3 months

Store below 25°C.

Keep the bottle in its carton box.

## **12. INSTRUCTIONS REGARDING DISPOSAL OF THE MEDICINAL PRODUCT/REMNANTS OF THE MEDICINAL PRODUCT AFTER USE:**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of as toxic waste, do not throw to sewer.

## **13. ADDITIONAL INFORMATION**

In addition to the active ingredients, the medicine contains: Liquid paraffin, colloidal anhydrous silica.

The medicine is a liquid suspension in a white plastic dropper bottle

Package size: 15ml

Producer: Elanco Animal Health, Eli Lilly, Wien, Austria

Registration holder: Euromar Ltd. P.O.B 1064 Ramat-Hasharon.

This leaflet has been checked and approved by the ministry of health in 03.2020

Registration number of the medicinal product in the National Drug Registry of the Ministry of Health:076-10-91829-00