

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

Do not use in animals with perforated ear drums since Polymyxin B is known to be a potential ototoxic agent.

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Do not use in cases of known hypersensitivity to the active substances or to any of the excipients.

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5. SIDE EFFECTS

Deafness and impaired hearing (mainly in elderly dogs) have been reported very rarely. 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).

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

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) 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 and ensure the product is fully resuspended before use.

9. WITHDRAWAL PERIOD

Not applicable.

10. WARNINGS

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

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 product should be discontinued and treatment with an appropriate alternative should be initiated

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.

Interaction with other medicinal products and other forms of interaction:

Do not use concomitantly with medicines that induce ototoxicity.

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. Discard unused material.

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 GmbH

Heinz-Lohmann- Str. 4, 27472 Cuxhaven, German

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

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

Revised in 10/2022 according to the Ministry of health guidelines.