1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Surolan Veterinary

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

	mg/ml
Active substances:	
Miconazole Nitrate	23
Prednisolone Acetate	5
Polymyxin B Sulfate	0.5293

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ear drops suspension and cutaneous suspension.
White suspension

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats

4.2 Indications for use, specifying the target species

Surolan is used in dogs and cats for the treatment of otitis and skin infections caused by fungi, yeasts, gram negative and gram positive bacteria. ear mites

4.3 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 listed in section 6.1

4.4 Special warnings for each target species

As the product is a prescription only medicine, treatment should be closely supervised by a veterinary practitioner.

4.5 Special precautions for use

i. Special precautions for use in animals

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 ~~during treatment~~.
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.

ii. 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 in pregnancy. Always wear single use disposable gloves when applying the product to animals.

4.6 Adverse reactions (frequency and seriousness)

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)

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il

4.7 Use during pregnancy, lactation or lay

Corticosteroids are not recommended for use in pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use concomitantly with medicines that induce ototoxicity

4.9 Amounts to be administered and administration route

This 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL

ATC vet code: QS02CA01

Pharmacotherapeutic group: Otologicals, Corticosteriods and antiinfectives in combination

5.1 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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Silica colloidal anhydrous
Liquid paraffin

6.2 Incompatibilities

None known

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials

Shelf life after first opening the immediate packaging: 3 months.

6.4. Special precautions for storage

Do not store above 25 °C

6.5 Nature and composition of immediate packaging

Bottle: 15 ml white, opaque low-density polyethylene squeeze dropper bottle.
Closure: White, opaque high-density polyethylene child resistant cap (screwfit) with tamper evident ring or white, opaque high-density polyethylene tamper evident (screw fit) cap.
Dropper (Dosing Device): White, low-density polyethylene and thermoplastic elastomer or white, low density polyethylene.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused product or waste materials should be disposed of in accordance with national requirements.

7. MANUFACTURER:

Elanco GmbH , Heinz-Lohmann- Str. 4, 27472 Cuxhaven, Germany

8. LICENSE HOLDER

Euromar Ltd.

P.O.B 1064

Ramat Hasharon

9. REGISTRATION NUMBER 076 10 91829 00/01

Revised in 09/2022 according to the Ministry of Health guidelines.