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Surolan Ear Drops and Cutaneous Suspension

Species: Cats, Dogs

Therapeutic indication:Pharmaceuticals: Antimicrobials: Topical preparations: Ear/eye/nose, Skin, **Pharmaceuticals: Antimicrobials:** Antifungal products, **Pharmaceuticals: Anti-inflammatory preparations:** Topical

Active ingredient: Miconazole Nitrate, Polymyxin B, Prednisolone

Product: Surolan® Ear Drops and Cutaneous Suspension

Product index: Surolan Ear Drops and Cutaneous Suspension

Incorporating:

Qualitative and quantitative composition

Active substances:

Miconazole Nitrate 23

Prednisolone Acetate 5

Polymyxin B Sulfate 0.5293

For a full list of excipients, see Pharmaceutical particulars.

Pharmaceutical form

Ear drops suspension and cutaneous suspension.

White suspension

Clinical particulars

Target species

Dogs and cats

Indications for use, specifying the target species

For the topical treatment of otitis externa and skin infections caused by Gram-positive bacteria e.g. *Staphylococcus aureus* and *Streptococcus* spp. and Gram-negative bacteria *Escherichia coli* and *Pseudomonas aeruginosa*.

For the topical treatment of otitis externa and skin infections caused by fungi and yeasts: *Trichophyton* spp., *Microsporum* spp., *Malassezia pachydermatis*, *Candida* spp.

For the topical treatment of otitis externa caused by the ear mite *Otodectes cynotis*.

The product also has anti-inflammatory and anti-pruritic activity.

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.

Special warnings for each target species

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

Special precautions for use

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.

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.

<u>Special precautions to be taken by the person administering the veterinary medicinal product to animals</u>

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.

Special precautions for the protection of the environment:

Not applicable

Other precautions

Not applicable

Adverse reactions (frequency and seriousness)

Dogs and cats:

Very rare

(< 1 animal / 10,000 animals treated, including isolated reports):

1Mainly in elderly dogs. If this occurs, treatment should be stopped. Decreased hearing or deafness is

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).

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also the last section of the package leaflet for contact details.

Use during pregnancy, lactation or lay

Corticosteroids are not recommended for use in pregnant animals.

Interaction with other medicinal products and other forms of interaction

Do not use concomitantly with medicines that induce ototoxicity.

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 Adverse Reaction section).

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

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

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

Withdrawal period(s)

Not applicable.

Pharmacological particulars

ATC vet code: QS02CA01

Pharmacotherapeutic group: Otologicals, Corticosteriods and antiinfectives in combination

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.

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.

Pharmaceutical particulars

List of excipients

Silica colloidal anhydrous

Liquid paraffin

Incompatibilities

None known

Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years:

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

Special precautions for storage

Store below 25 °C

Nature and **composition of immediate packaging**

Bottle: 15 ml or 30 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.

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

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Marketing Authorisation Holder (if different from distributor)

Elanco GmbH,

Heinz-Lohmann Strasse 4,

D-27472 Cuxhaven,

Germany

Marketing Authorisation Number

GB: Vm 52127/5083

NI: Vm 52127/3018

Significant changes

Date of the first authorisation or date of renewal

Date of first authorisation:

UK:05 September 1985

Date of revision of the text

May 2025

Any other information

Veterinary medicinal product subject to prescription

Legal category

Legal category:POM-V

GTIN

GTIN description:SUROLAN 1X15ML DROPS GB-IE

GTIN:05420036902911

GTIN description:SUROLAN 1X30ML DROPS GB-IE

GTIN:05420036903055