1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Surolan Ear Drops and Cutaneous Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients:

Qualitative composition of excipients and other constituents
Silica colloidal anhydrous
Liquid paraffin

White suspension

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats

3.2 Indications for use for each 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 veterinary medicinal product also has anti-inflammatory and anti-pruritic activity.

3.3 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.

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 veterinary medicinal product should be discontinued and treatment with an appropriate alternative should be initiated.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Do not handle the veterinary medicinal product if you are allergic to the ingredients in the veterinary medicinal 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 veterinary medicinal product to animals.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Deafness[1] Impaired hearing[1]

[1] Mainly in elderly dogs. 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).

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Corticosteroids are not recommended for use in pregnant animals.

3.8 Interaction with other medicinal products and other forms of interaction

Do not use concomitantly with medicines that induce ototoxicity.

3.9 Administration routes and dosage

This veterinary medicinal product is for topical administration. Shake the bottle vigorously and ensure the veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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 3.6).

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QS02CA01

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 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.

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

Bottle: 15 ml or 30 ml white low-density polyethylene squeeze dropper bottle.
Closure: White, opaque high-density polyethylene child resistant cap (screw fit) 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.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA22020/032/001

8. DATE OF FIRST AUTHORISATION

01/10/1988

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

MM/2022

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).