SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Surolan Ear Drops and Cutaneous Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients:
For the 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

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.

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.

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.
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

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

iii) Other precautions

Not applicable

4.6 Adverse reactions (frequency and seriousness)

Dogs and cats:

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

[1]Mainly in elderly dogs. 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).

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.

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 Amount(s) 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 PROPERTIES

Pharmacotherapeutic group: Otologicals, Corticosteriods and antiinfectives in combination ,

ATCvet Code: QS02CA01

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 Major Incompatibilities

None known.

6.3 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.

6.4 Special precautions for storage

Store below 25 °C

6.5 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.

6.6 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.

7. MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann Strasse 4
D-27472 Cuxhaven
Groden
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 52127/5083

9. DATE OF FIRST AUTHORISATION

05 September 1985

10. DATE OF REVISION OF THE TEXT

April 2025

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription

Approved 29 April 2025
Gavin Hall