

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Surolan Ear Drops and Cutaneous Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

	<u>mg/ml</u>
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

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.

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 likely variability (time, geographical) in the occurrence of resistance of bacteria for Polymyxin B, bacteriological sampling and susceptibility testing are recommended.

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)

Long-term use of topical steroids may cause skin thinning and delay wound healing.

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

None known

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

The product is applied topically. No toxic side effects have been observed after accidental intake by licking.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL

ATC vet code: QS02CA01

Pharmacotherapeutic group: Otologicals, Corticosteroids 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

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

Do not store above 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

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

7. MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

8. MARKETING AUTHORISATION NUMBERS

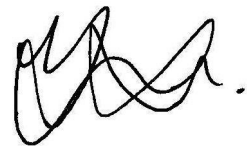
UK: Vm 00879/4171
IE: VPA 10545/001/001

9. DATE OF FIRST AUTHORISATION

Date of first authorisation:
UK: 05 September 1985
IE: 01 October 1988

10. DATE OF REVISION OF THE TEXT

September 2020

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 24 September 2020