PARTICULARS TO APPEAR ON THE OUTER PACKAGE
15ml & 30ml CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Surolan Ear Drops and Cutaneous Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active ingredients per ml:
miconazole nitrate 23 mg, polymyxin B sulfate 0.5293 mg, prednisolone acetate 5 mg

3. PACKAGE SIZE

15 ml
30 ml

4. TARGET SPECIES

Cats and dogs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
FOR EXTERNAL USE ONLY

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within three months.

9. SPECIAL STORAGE PRECAUTIONS

Shake vigorously and ensure the product is fully resuspended before use.
Do not store above 25 ºC.
Keep the dropper bottle in the outer carton.
Discard unused material.
Date to be discarded:

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

14. MARKETING AUTHORISATION NUMBERS

Vm 52127/5083

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.
Operator Warnings:
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 when used in pregnancy.
Always wear single use disposable gloves when applying the product to animals.
Do not handle the product if you are allergic to any of the ingredients in the product.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

UK only:
POM-V

To be supplied only on veterinary prescription

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
15ml & 30ml BOTTLE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Surolan Ear Drops and Cutaneous Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active ingredients per ml:
miconazole nitrate 23 mg, polymyxin B sulfate 0.5293 mg, prednisolone acetate 5 mg

3. TARGET SPECIES

Cats and dogs

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}

7. SPECIAL STORAGE PRECAUTIONS

Keep the dropper bottle in the outer carton.
Do not store above 25 ºC.

8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

9. BATCH NUMBER

Lot {number}

10. PACKAGE SIZE

15 ml
30 ml

11. INDICATION(S)

12. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

13. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

14. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

UK only:
FOR ANIMAL TREATMENT ONLY.
POM-V
To be supplied only on veterinary prescription

15. MARKETING AUTHORISATION NUMBER(S)

Vm 52127/5083

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Surolan ear drops and cutaneous suspension

2. COMPOSITION

Each ml of ear drops and cutaneous suspension contains miconazole nitrate 23 mg, prednisolone acetate 5 mg and polymyxin B sulfate 0.5293 mg.

White suspension

3. TARGET SPECIES

Cats and dogs

4. INDICATIONS FOR USE

Ear and skin treatment for cats and dogs.
The veterinary medicinal product is used in cats and dogs for the treatment of ear and skin infections caused by fungi, yeasts, Gram-negative and Gram-positive bacteria and ear mites.
The veterinary medicinal product will control infection due to, for example:

Gram-positive bacteria	**Fungi and yeasts**	**Ear mites**
Staphylococcus aureus	*Trichophyton* spp.	*Otodectes cynotis*
Streptococcus spp.	*Microsporum* spp.	
Gram-negative bacteria	*Malassezia pachydermatis*	
E.coli	*Candida* spp.	
Pseudomonas aeruginosa		

5. 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.

6. SPECIAL WARNING(S)

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

Special precautions for safe use in the target species:
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

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

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
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 when used in pregnancy. **Always wear single use disposable gloves when applying the veterinary medicinal product to animals.** Do not handle the veterinary medicinal product if you are allergic to any of the ingredients in the veterinary medicinal product.

Interactions with other medicinal products and other forms of interaction:
Do not use concomitantly with medicines that induce ototoxicity.

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

Major incompatibilities:
None known.

7. 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. 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For external use only.
This veterinary medicinal product is for topical administration.
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 a day.
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 obtain optimum distribution of the veterinary medicinal product.
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.
Do not discontinue the treatment until a few days after complete disappearance of the clinical symptoms.
In some obstinate cases, 2 to 3 weeks treatment may be necessary.
Where mite infestation is present, consideration should be given to treating both ears even if infestation is only apparent in one ear.

9. ADVICE ON CORRECT ADMINISTRATION

Shake the bottle vigorously and ensure the veterinary medicinal product is fully resuspended before use.

10. WITHDRAWAL PERIOD(S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25 °C.
Keep the dropper bottle in the outer carton.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: three months.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

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.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Presentation
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.

Vm 52127/5083

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:
Elanco GmbH
Heinz-Lohmann Strasse 4
D-27472 Cuxhaven
Groden
Germany

Manufacturer responsible for batch release:
Lusomedicamenta, Sociedade Técnica Farmacêutica, S.A.,
Estrada Consiglieri Pedroso, n.° 66, 69-B Queluz de Baixo 2730-055 Barcarena
Portugal.

17. OTHER INFORMATION

Properties
Miconazole is a synthetic imidazole derivative with a pronounced antifungal effect and a potent activity against Gram-positive bacteria. Polymyxin B is an antibiotic with a bactericidal effect against Gram-negative bacteria. To these two substances, prednisolone has been added to provide anti-inflammatory and antipruritic activities.

UK Only:
Legal category: POM-V

Approved 29 April 2025
Gavin Hall