

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

13 ml & 15 ml CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Surolan Ear Drops and Cutaneous Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Ear Drops and Cutaneous Suspension

4. PACKAGE SIZE

15 ml
30 ml

5. TARGET SPECIES

Cats and dogs

6. INDICATION(S)

Ear and skin treatment for cats and dogs
For bacterial, fungal and ear mite infections
Also provides anti-inflammatory & antipruritic activity

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. 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.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

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

Do not store above 25 °C.

Keep the dropper bottle in the outer carton.

Once opened use within three months.

Discard unused material.

Date to be discarded:

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

FOR EXTERNAL USE ONLY

To be supplied only on veterinary prescription

UK only

Legal category: POM-V

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4171

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

13ml & 15ml BOTTLE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Surolan Ear Drops and Cutaneous Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Ear Drops and Cutaneous Suspension

4. PACKAGE SIZE

15 ml
30 ml

5. TARGET SPECIES

Cats and dogs

6. INDICATION(S)

Ear and skin treatment for cats and dogs

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

FOR ANIMAL TREATMENT ONLY.

UK: POM-V

To be supplied only on veterinary prescription

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4171

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

B. PACKAGE LEAFLET

**PACKAGE LEAFLET:
Surolan Ear Drops and Cutaneous Suspension**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
AND OF THE MANUFACTURING AUTHORISATION HOLDER
RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

Janssen Pharmaceutica NV, Beerse, Belgium
Or
Lusomedicamenta, Sociedade Técnica Farmacêutica, S.A.,
Estrada Consiglieri Pedroso, n.º 66, 69-B Queluz de Baixo 2730-055 Barcarena
Portugal.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Surolan ear drops and cutaneous suspension

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER
INGREDIENT(S)**

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

4. INDICATION(S)

Ear and skin treatment for cats and dogs.

Surolan 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. Surolan will control infection due to, for example:

Gram-positive bacteria

Staphylococcus aureus
Streptococcus spp.

Gram-negative bacteria

E.coli
Pseudomonas aeruginosa

Fungi and yeasts

Trichophyton spp.
Microsporum spp.

Malassezia pachydermatis

Candida spp.

Ear mites

Otodectes cynotis

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. ADVERSE REACTIONS

Deafness and impaired hearing (mainly in elderly dogs) have been reported very rarely. 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).

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats and dogs

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

For external use only.

This 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 Surolan 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 product.

Skin: Having ensured the area to be treated is clean, apply a few drops of Surolan (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 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 after the expiry date stated on the label and carton. The date refers to the last day in that month.

Once opened use within three months. Discard unused material.

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified above, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

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

Corticosteroids are not recommended for use in pregnant animals. As Surolan is a prescription only medicine, treatment should be closely supervised by a veterinary practitioner.

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.

Interaction with other medicinal products and other forms of interaction:

Do not use concomitantly with medicines that induce ototoxicity.

FOR ANIMAL TREATMENT ONLY

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2022

15. OTHER INFORMATION

Presentation

15 ml or 30 ml dropper bottle.
Not all pack sizes may be marketed.

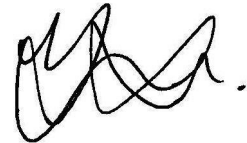
Properties

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.

To be supplied only on veterinary prescription

Marketing authorisation number

UK only Vm 00879/4171 Legal category: POM-V
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Approved: 04 August 2022