ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Recicort 1.77 mg/ml + 17.7 mg/ml ear drops, solution for dogs and cats
triamcinolone acetonide / salicylic acid

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:
Triamcinolone acetonide 1.77 mg
Salicylic acid 17.7 mg

3. PHARMACEUTICAL FORM

Ear drops, solution.

4. PACKAGE SIZE

20 ml

5. TARGET SPECIES

Dogs and cats.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For auricular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

This product can cause severe adverse reactions. Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the immediate packaging: 3 months.
Once opened, use by….

11. SPECIAL STORAGE CONDITIONS

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

Disposal: read package leaflet

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

For animal treatment only.
To be supplied only on veterinary prescription.

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

Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 41821/4039

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LDPE Container: 20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Recicort 1.77 mg/ml + 17.7 mg/ml ear drops
triamcinolone acetonide / salicylic acid

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Triamcinolone acetonide 1.77 mg/ml
Salicylic acid 17.7 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml

4. ROUTE(S) OF ADMINISTRATION

For auricular use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:
Once opened, use by….

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Recicort 1.77 mg/ml + 17.7 mg/ml ear drops, solution for dogs and cats

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

Marketing authorisation holder
Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer responsible for batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Recicort 1.77 mg/ml + 17.7 mg/ml ear drops, solution for dogs and cats
triamcinolone acetonide / salicylic acid

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

1 ml contains:

Active substances:
Triamcinolone acetonide 1.77 mg
Salicylic acid 17.7 mg

Clear colourless solution.

4. INDICATION(S)

Treatment of otitis externa.
Symptomatic treatment of seborrhoeic dermatitis of the auricle.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to corticosteroids, salicylic acid or to any of the excipients.
Do not use in animals with perforated tympanic membrane.Do not use in dogs with demodicosis

6. ADVERSE REACTIONS

Prolonged and extensive use of topical corticosteroid preparations is known to trigger local and systemic effects, including suppression of adrenal function, thinning of the epidermis and delayed healing.

In rare cases redness and skin scaling have been reported.

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 side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}

7. TARGET SPECIES

Dogs and cats.

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

For ear and cutaneous (auricle)use.

Ear canal
Clean the external ear canal and auricle. The recommended treatment dose is 8-10 drops instilled into the affected external ear canal(s), once or twice daily. Massage the ear and the auditory canal thoroughly yet gently to ensure proper distribution of the product.
The treatment dose (8-10 drops per ear; once or twice daily) should not exceed 7 drops per kg bodyweight per day. Care should be taken not to exceed this amount, particularly when treating smaller animals or when both ears require treatment.
Treatment should be continued without interruption until a few days after complete disappearance of the clinical symptoms but no longer than 14 days. If the otitis externa does not improve after 3 days of treatment the treatment should be re-evaluated.

Auricle
For the treatment of auricular seborrhoeic dermatitis, apply twice a day a sufficient number of drops onto the auricular surface so that when spread, the affected area is covered. If necessary, rub the area gently to ensure the veterinary medicinal product reaches all the affected skin. Let dry. In severe cases the effect can be increased by applying a second and third layer immediately after the drying of the first layer provided that the total number of applied drops does not exceed the maximum dose of 7 drops per kg body weight per day. Care should be taken not to exceed this dose when treating smaller dogs and cats.
Treatment should be continued without interruption until a few days after complete disappearance of the clinical symptoms but no longer than 14 days.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary product does not require any special storage conditions.Shelf life after first opening the immediate packaging: 3 months
Do not use this veterinary medicinal product after the expiry date which is stated on the container after EXP.
The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species
For an effective treatment of otitis externa it is essential that the ear canal is meticulously cleaned and dried before first treatment to remove cerumen and/or exudate. Excess hair around the treatment area should be clipped if necessary.
For an effective treatment of seborrhoeic dermatitis existing scale and or exfoliative debris should be removed. Hair surrounding or covering the lesions may need to be clipped to enable the veterinary medicinal product to reach the affected skin.
Seborrhoeic dermatitis may be a primary disorders, but can also occur as a result of underlying disorders or disease processes (e.g. allergic disorders, endocrine disorders, neoplasia) while otitis externa is only very rarely primary and occurs mainly as a result of different underlying causes (predisposing and perpetuating factors, neoplasia). Therefore, it is essential to identify any underlying disease process and initiate specific treatment, if considered necessary.

Furthermore, infections (bacterial, parasitic or fungal) commonly occur concurrently with seborrhoeic dermatitis or otitis externa and should be identified prior to the start of the treatment and treated specifically, if considered necessary.

Special precautions for use in animals
The maximum dose that may be administered is 7 drops per kg body weight per day. The recommended treatment dose (8-10 drops per ear; once or twice daily) should not exceed 7 drops per kg bodyweight per day. Care should be taken not to exceed this amount, particularly when treating smaller animals or when both ears require treatment.
In cases of otitis externa with an infectious component (bacterial, parasitic or fungal) specific treatment should be administered if considered necessary.
Systemic corticosteroid effects are possible, especially when the product is ingested by licking.
Oral ingestion (including licking) of the product by treated animals or animals having contact with treated animals should be avoided. Additional corticosteroid treatment should be used only according to the benefit/risk assessment of the responsible veterinarian. Use with caution in animals with suspected or confirmed endocrine disorders (i.e. diabetes mellitus; hypo- or hyperthyroidism hyperadrenocorticism etc.).
Since glucocorticosteroids are known to slow growth, use in young animals (under 7 months of age) should be based on a benefit/risk assessment by the attending veterinarian and subject to regular clinical re-evaluations.
Care should be taken to avoid contact with eyes. Do not apply the veterinary medicinal product on damaged skin. If hypersensitivity to any of the components occurs, the ear should be thoroughly washed.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
This product contains triamcinolone acetonide, salicylic acid and ethanol and may be harmful to children after accidental ingestion. Do not leave the product unattended. In case of accidental ingestion seek medical advice immediately and show the package leaflet or label to the physician.

This product may be irritating to skin or induce hypersensitivity reactions. People with known hypersensitivity to corticosteroids or salicylic acid should avoid contact with the product. Avoid skin contact with the product. Wear single-use impermeable gloves when handling the product including rubbing in the affected skin of the animal. If contact occurs, wash hands or exposed skin and seek medical advice in case of hypersensitivity reactions or if irritation persists.

This product may be irritating to the eyes. Avoid contact with the eyes including hand-to-eye contact. If contact occurs, rinse with clean water. If eye irritation persists, seek medical advice and show the package leaflet or label to the physician.

This product may be harmful to the unborn child. As the product can be absorbed through the skin, pregnant women and women of childbearing potential should not handle this product or restrain the animal during treatment and should avoid contact with the ears of the treated animal until at least 4 hours after the application.

Treated animals should not be handled and children should not be allowed to play with treated animals until the application site is dry. It is recommended that recently treated animals should not be allowed to sleep with owners, especially children.

Pregnancy and lactation
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit/risk assessment of the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction
No data available. Use of additional corticosteroid treatment only according to the benefit/risk assessment of the responsible veterinarian.

Overdose (symptoms, emergency procedures, antidotes)
Prolonged use of high doses of triamcinolone can induce adrenal insufficiency.

Incompatibilities
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

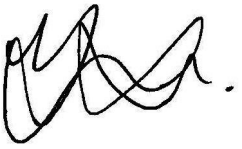
Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2021

15. OTHER INFORMATION

20 ml container.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.



Approved: 14 March 2022