PARTICULARS TO APPEAR ON THE OUTER PACKAGE – Outer cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Recicort 1.77 mg/ml + 17.7 mg/ml ear drops, solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Triamcinolone acetonide	1.77 mg
Salicylic acid	17.7 mg

3. PACKAGE SIZE

20 ml

4. TARGET SPECIES

Dogs and cats

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

For auricular use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months.
Once opened, use by….

9. SPECIAL STORAGE PRECAUTIONS

This veterinary product does not require any special storage conditions.

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 OF THE MARKETING AUTHORISATION HOLDER

Le Vet. Beheer B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 41821/5020

15. BATCH NUMBER

Lot{number}

16. SPECIAL WARNING(S), IF NECESSARY

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

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS - LDPE Container: 20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Recicort

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}:
Once opened use within 3 months
Once opened, use by….

5. ROUTE(S) OF ADMINISTRATION

For auricular use.

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only. POM-V

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Each ml contains:

Active substances:

Triamcinolone acetonide	1.77 mg
Salicylic acid	17.7 mg

Clear colourless solution.

3. TARGET SPECIES

Dogs and cats

4. INDICATIONS FOR USE

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. SPECIAL WARNINGS

Special precautions for safe use in the 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.

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:
Prolonged use of high doses of triamcinolone can induce adrenal insufficiency.

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

7. ADVERSE EVENTS

Dogs and cats:

Rare (1 to 10 animals / 10,000 animals treated)	Application site reddening, Application site skin scaling
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Skin thinning[a] Suppression of adrenal function[a,b]
Undetermined frequency (cannot be estimated from the available data)	Delayed healing[a]

[a] Local and systemic effects are known to be triggered with prolonged and extensive use of topical corticosteroid preparations.
[b] Undetermined frequency for target species cat.

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: {national system details}.

8. DOSAGE FOR EACH SPECIES, ROUTES 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 PERIODS

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 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. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBER AND PACK SIZES

Marketing authorisation number:
Vm 41821/5020

Packaging:
Carton containing a 20 ml dropper container

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:
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

Local representatives and contact details to report suspected adverse reactions:
Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom
Tel: +44 (0) 1939 211200

17. OTHER INFORMATION

POM-V

For animal treatment only

Gavin Hall
Approved: 22 December 2024