[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Recicort 1.77 mg/ml + 17.7 mg/ml ear drops, solution for dogs and cats
Recicort vet 1.77 mg/ml + 17.7 mg/ml ear drops, solution for dogs and cats (DK, FI, IS, NO, SE, EE, LT, LV, PL)
Recicort ear drops, solution for dogs and cats (FR)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Triamcinolone acetonide 1.77 mg
Salicylic acid 17.7 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Ethanol (96 per cent)	660.5 mg
Benzalkonium chloride	0.50 mg
Purified water	

Clear colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

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

3.3 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.

3.4 Special warnings

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 disorder, 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 veterinary medicinal product is ingested by licking.
Oral ingestion (including licking) of the veterinary medicinal 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 hyper-thyroidism, 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 veterinary medicinal product contains triamcinolone acetonide, salicylic acid and ethanol and may be harmful to children after accidental ingestion. Do not leave the veterinary medicinal product unattended. In case of accidental ingestion seek medical advice immediately and show the package leaflet or label to the physician.

This veterinary medicinal product may be irritating to skin or induce hypersensitivity reactions. People with known hypersensitivity to corticosteroids or salicylic acid should avoid contact with the veterinary medicinal product. Avoid skin contact with the veterinary medicinal product. Personal protective clothing consisting of single use impermeable gloves should be worn when handling the veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product may be harmful to the unborn child. As the veterinary medicinal product can be absorbed through the skin, pregnant women and women of childbearing potential should not handle this veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 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] Adrenal suppression[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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

3.8 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.

3.9 Administration routes and dosage

Auricular 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 veterinary medicinal 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QS02BA99

4.2 Pharmacodynamics

Triamcinolone acetonide in this concentration is a moderately potent steroid. Corticosteroids have an anti-inflammatory and vasoconstrictive action. They suppress the inflammatory response and the symptoms of various disorders often associated with itching. The treatment however does not cure the underlying diseases.
Salicylic acid has an acidifying effect and also has a cerumenolytic effect through its keratolytic properties.

4.3 Pharmacokinetics

Triamcinolone acetonide can be absorbed through the skin, and, although the concentration is low, a systemic action is not excluded. After systemic absorption, triamcinolone is 60-70% bound to plasma proteins. Triamcinolone is metabolised primarily in the liver. The main metabolite is 6β-hydroxytriamcinolone, which is excreted mainly in the form of sulfates and glucuronides in urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 30 months.
Shelf-life after first opening the immediate packaging: 3 months

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Carton containing a 20 ml white, low density polyethylene dropper container with high density polyethylene cap.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet Beheer B.V.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

<Date of first authorisation:> <{DD/MM/YYYY}> <{DD month YYYY}.>

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

LABELLING AND PACKAGE LEAFLET

A. LABELLING

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 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. INDICATIONS

6. ROUTES OF ADMINISTRATION

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

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

15. BATCH NUMBER

Lot{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LDPE Container: 20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Recicort

2. 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….

B. PACKAGE LEAFLET

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

Excipient(s):

Ethanol (96 per cent)	660.5 mg
Benzalkonium chloride	0.50 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 warnings:
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 safe use in the target species:
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. Personal protective clothing consisting of single use impermeable gloves should be worn when handling the veterinary medicinal 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] Adrenal suppression[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 <or the local representative of 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

Auricular 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 or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. 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 numbers and pack sizes

Marketing authorisation number(s):

Packaging:
Carton containing a 20 ml dropper container

15. Date on which the package leaflet was last revised

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder <and contact details to report suspected adverse reactions>:
Le Vet. Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands
Phone number: +31 348 563434

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>:>

17. Other information