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

1 ml contains:

Active substances:

Triamcinolone acetonide	1.77 mg
Salicylic acid	17.7 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ear drops, solution.
Clear colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

Otitis externa.
Symptomatic treatment of seborrhoeic dermatitis of the auricle.

4.3 Contraindications

Do not use in case of hypersensitivity to corticosteroids, salicylic acid or to any of the excipients.
Do not use in animals with perforated tympanic membrane, as the product may be ototoxic. Do not use in dogs with demodicosis.

4.4 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.

Otitis externa and seborrhoeic dermatitis may be primary disorders, but can also occur as a result of underlying disorders or disease processes (e.g. allergic disorders, endocrine disorders, neoplasia). Furthermore, infections (bacterial, parasitic or fungal) commonly occur concurrently with seborrhoeic dermatitis or may complicate cases of otitis externa. Therefore it is essential to identify any underlying disease process and initiate specific treatment if considered necessary.

4.5 Special precautions for use

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 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 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.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during 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.

4.8 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.

4.9 Amounts to be administered and administration route

For 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Corticosteroids, moderately potent, other combinations
ATCvet code: QD07XB02

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol (96 per cent)
Benzalkonium chloride
Purified water

6.2 Incompatibilities

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

6.3 Shelf life

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

6.4 Special precautions for storage

This veterinary product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 41821/4039

9. DATE OF FIRST AUTHORISATION

22 March 2017

10. DATE OF REVISION OF THE TEXT

May 2019

Approved: 09 May 2019