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Dechra Veterinary Products

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Recicort® 1.77 mg/ml + 17.7 mg/ml Ear Drops, Solution for Dogs and Cats

Species: Cats, Dogs

Therapeutic indication:Pharmaceuticals: Antimicrobials: Topical preparations: Ear/eye/nose

Active ingredient: Triamcinolone Acetonide

Product: Recicort® 1.77 mg/ml + 17.7 mg/ml Ear Drops, Solution for Dogs and Cats

Product index: Recicort 1.77 mg/ml + 17.7 mg/ml Ear Drops, Solution for Dogs and Cats

Incorporating:

Qualitative and quantitative composition

Each ml contains:

Active substances:

Triamcinolone acetonide 1.77 mg

Salicylic acid 17.7 mg

Excipients:

Ethanol (96 per cent)

Benzalkonium chloride

Purified water

Pharmaceutical form

Ear drops, solution. Clear colourless solution.

Clinical particulars

Target species

Dogs and cats.

Indications for use, specifying the target species

Treatment of otitis externa.

Symptomatic treatment of seborrhoeic dermatitis of the auricle.

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.

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 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.

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 body weight 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.

Special precautions for the protection of the environment

Not applicable.

Other precautions

Not applicable.

Adverse reactions (frequency and seriousness)

Dogs and cats:

Rare Application site redde

(1 to 10 animals / 10,000 animals treated)

Very rare	Skin thinninga
(<1 animal / 10,000 animals treated, including isolated reports):	Suppression of adrenal funct
Undetermined frequency (cannot be estimated from the available data)	Delayed healinga

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.

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.

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.

Amount(s) to be administered and administration route

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 body weight 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.

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

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

Withdrawal period(s)

Not applicable

Pharmacological particulars

Pharmacotherapeutic group: Corticosteroids, moderately potent, other combinations

ATCvet code: QD07XB02

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.

Pharmacokinetic properties

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.

Pharmaceutical particulars

Excipients

Ethanol (96 per cent)

Benzalkonium chloride

Purified water

Major incompatibilities

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

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.

Special precautions for storage

This veterinary product does not require any special storage conditions.

Nature and composition of immediate packaging

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

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

Medicines should not be disposed of via wastewater. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Marketing Authorisation Holder (if different from distributor)

Le Vet Beheer BV, Wilgenweg 7, 3421 TV Oudewater, The Netherlands.

Marketing Authorisation Number

GB: Vm 41821/5020

NI: Vm 41821/3014

Significant changes

Date of the first authorisation or date of renewal

22 March 2017

Date of revision of the text

March 2024

Any other information

For animal treatment only. To be supplied only on veterinary prescription. Keep out of the sight and reach of children.

GB: Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

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

Legal category

NOAH Compendium

Legal category:POM-V

GTIN

GTIN description: Recicort 1.77 mg/ml + 17.7 mg/ml Ear Drops, Solution for Dogs and Cats

GTIN:08718469445752