

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dermanolon 1.77 mg/ml + 17.7 mg/ml cutaneous spray, solution for dogs and cats

Dermanolon vet 1.77 mg/ml + 17.7 mg/ml cutaneous spray, solution for dogs and cats (DK, FI, IS, NO, SE, EE, LT, LV, PL)

Dermanolon cutaneous spray, 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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cutaneous spray, solution.

Clear colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

Symptomatic treatment of seborrhoeic dermatitis

4.3 Contraindications

Do not use in cases of hypersensitivity to corticosteroids, salicylic acid or to any of the excipients

Do not use on cutaneous ulcers.

Do not use in dogs with demodicosis.

Do not administer to animals weighing less than 3.5 kg body weight.

4.4 Special warnings for each target species

At the beginning of treatment, 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). Furthermore, infections (bacterial, parasitic or fungal) commonly occur concurrently with seborrhoeic dermatitis. 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

As the minimum bodyweight for the treatment is 3,5 kg, this product will not be suitable for use in certain patients, such as smaller dogs and cats or those with extensive lesions. Please check maximum recommended dose in section 4.9.

Systemic corticosteroid effects are possible, especially when the product is used under an occlusive dressing, on extensive skin lesions, with increased blood flow, or if 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 precaution 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.

Do not apply in the eyes or on the mucosa. Do not apply the veterinary medicinal product on damaged skin.

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 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 treated animal until at least 4 hours after the application.

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 or restraining the animal during treatment. 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 after inhalation, especially for people with asthma. Spray in well-ventilated area. Avoid breathing in the spray-mist.

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.

4.7 Use during pregnancy and lactation

The veterinary medicinal product should not be used during pregnancy and lactation because of possible absorption of triamcinolone acetonide, especially if larger areas of the skin need to be treated.

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

Cutaneous use.

Treatment dose is 1 spray pump activation per 1.75 kg bodyweight; to be administered twice a day.

As the product should be applied twice daily, animals should weigh at least 3.5 kg to allow for 2 spray pump activations per day (1 spray pump activation twice daily).

Make sure the opening of the spray pump points to the area to be treated. Brush the pet's hair against the natural fur line, then spray the product by holding the pump approximately 10 cm from the area to be treated. Care should be taken to avoid spraying near the face of the animal.

If necessary rub the area gently to ensure the veterinary medicinal product reaches all the affected skin. Let dry. In severe cases in dogs, 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 spray activations does not exceed the maximum number (1 spray pump activation per 1.75 kg; to be administered twice a day). One spray pump activation delivers approximately 0.2 ml of product over a circular area of approximately 10 cm diameter

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 a keratolytic and acidifying effect.

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 6 β -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 Major 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 immediate packaging: 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 50 or 75 ml white, high density polyethylene container with spray pump and a styrene acrylonitrile polymer cap. Not all pack sizes may be marketed.

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(S)

Vm 41821/4038

9. DATE OF FIRST AUTHORISATION

Date of first authorisation: 27-01-2017

10. DATE OF REVISION OF THE TEXT

January 2022