1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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)	
Benzalkonium chloride	0.4415 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

Symptomatic treatment of seborrhoeic dermatitis.

3.3 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.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

As the minimum bodyweight for the treatment is 3.5 kg, this veterinary medicinal 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 3.9.
Systemic corticosteroid effects are possible, especially when the veterinary medicinal product is used under an occlusive dressing, on extensive skin lesions, with increased blood flow, or if 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 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 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 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 treated animal until at least 4 hours after the application.

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 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 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 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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs and cats:

Undetermined frequency (cannot be estimated from the available data)	Skin thinning[a] Delayed healing[a] Adrenal suppression[a]

[a] Local and systemic effects are known to be triggered with prolonged and extensive use of topical corticosteroid preparations.

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. Do not use during pregnancy and lactation.

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

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

As the veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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.

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: QD07XB02

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 a keratolytic and acidifying effect.

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 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.

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)

VPA10475/026/001

8. DATE OF FIRST AUTHORISATION

10/02/2017

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

23/03/2024

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).