ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

Cardboard box
HDPE container 75 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dermanolon 1.77 mg/ml + 17.7 mg/ml cutaneous spray, solution for dogs and cats
triamcinolone acetonide / salicylic acid

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Triamcinolone acetonide 1.77 mg
Salicylic acid 17.7 mg

3. PHARMACEUTICAL FORM

Cutaneous spray, solution.

4. PACKAGE SIZE

75 ml
50 ml

5. TARGET SPECIES

Dogs and cats.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For cutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

This product can cause severe adverse reactions. Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}>
Shelf life after first opening the immediate packaging: 3 months.
Once opened, use by….

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 41821/5019

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Container: 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dermanolon 1.77 mg/ml + 17.7 mg/ml cutaneous spray, solution
triamcinolone acetonide / salicylic acid

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Triamcinolone acetonide 1.77 mg/ml
Salicylic acid 17.7 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml

4. ROUTE(S) OF ADMINISTRATION

For cutaneous use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:
Once opened, use by….

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer for the batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dermanolon 1.77 mg/ml + 17.7 mg/ml cutaneous spray, solution for dogs and cats
triamcinolone acetonide / salicylic acid

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substances:
Triamcinolone acetonide 1.77 mg
Salicylic acid 17.7 mg

Clear colourless solution.

4. INDICATION(S)

Symptomatic treatment of seborrhoeic dermatitis.

5. 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.

6. ADVERSE REACTIONS

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.

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 inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}

7. TARGET SPECIES

Dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Cutaneous use. The product should be applied twice a day.
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).

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

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

10. WITHDRAWAL PERIOD

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 WARNING(S)

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.

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 “Dosage for each species, route(s) and method of administration”.
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, hyperadrenocorticcism etc.). Since glucocorticosteroids are known to slow growth, use in young animals (under 7 months of age) should be based on a benefit/riskassessment 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.

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

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 (symptoms, emergency procedures, antidotes)
Prolonged use of high doses of triamcinolone can induce adrenal insufficiency.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2021

15. OTHER INFORMATION

50 ml and 75 ml containers.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 21 January 2022