ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alcort 0.584 mg/ml cutaneous spray, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Hydrocortisone aceponate 0.584 mg equivalent to 0.460 mg hydrocortisone

Excipient:

Qualitative composition of excipients and other constituents
Propylene glycol methyl ether

A clear, colourless to slightly yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For symptomatic treatment of inflammatory and pruritic dermatoses in dogs.
For alleviation of clinical signs associated with atopic dermatitis in dogs.

3.3 Contraindications

Do not use on cutaneous ulcers.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Clinical signs of atopic dermatitis such as pruritus and skin inflammation are not specific for this disease and therefore other causes of dermatitis such as ectoparasitic infestations and infections which cause dermatological signs should be ruled out before treatment is started, and underlying causes should be investigated.
In the case of concurrent microbial disease or parasitic infestation, the dog should receive appropriate treatment for such condition.
In the absence of specific information, the use in animal suffering from Cushing's syndrome shall be based on the risk-benefit assessment.
Since glucocorticosteroids are known to slow growth, use in young animals (under 7 months of age) shall be based on the risk-benefit assessment and subject to regular clinical evaluations.
Total body surface treated should not exceed approximately 1/3 of the dog's surface corresponding for

example to a treatment of two flanks from the spine to the mammary chains including the shoulders and the thighs. See also section 3.10. Otherwise, use only according to the risk-benefit assessment of the responsible veterinary surgeon and subject the dog to regular clinical evaluations as further described in section 3.9.
Care should be taken to avoid spraying into the eyes of the animal.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The active substance is potentially pharmacologically active at high doses of exposure.
The formulation may cause eye irritation following accidental ocular contact.
The formulation is flammable.

Wash hands after use. Avoid contact with eyes.
To avoid skin contact, recently treated animals should not be handled until the application site is dry.
To avoid inhalation of the product, apply the spray in a well-ventilated area.

Do not spray on naked flame or any incandescent material.
Do not smoke while handling the veterinary medicinal product.
Replace the bottle in the outer carton and in a safe place out of the sight and the reach of children immediately after use.

In case of accidental skin contact, avoid hand-to-mouth contact and wash the exposed area immediately with water.
In case of accidental eye contact, rinse with abundant quantities of water.
If eye irritation persists, seek medical advice.
In case of accidental ingestion, especially by children, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

The solvent in this product may stain certain materials including painted, varnished or other household surfaces or furnishings. Allow the application site to dry before permitting contact with such materials.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site erythema; Application site pruritus

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. Systemic absorption of hydrocortisone aceponate being negligible, it is unlikely for teratogenic, foetotoxic, maternotoxic effects to happen at the recommended dosage in dogs.

Use only according to the benefit-risk assessment by the responsible veterinarian.

Fertility:

Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

No data available.

In the absence of information, it is recommended not to apply other topical preparations simultaneously on the same lesions.

3.9 Administration routes and dosage

For cutaneous use.

Before administration, screw the pump spray on the bottle.
The veterinary medicinal product is then applied by activating the pump spray, from a distance of about 10 cm of the area to be treated.
The recommended dosage is 1.52 µg of hydrocortisone aceponate/cm^2 of affected skin per day. This dosage can be achieved with two pump spray activations over a surface to be treated equivalent to a square of 10 cm x 10 cm.
Presented as a volatile spray, this veterinary medicinal product does not require any massage.

- For treatment of inflammatory and pruritic dermatoses, repeat the treatment daily for 7 consecutive days.
In case of conditions requiring an extended treatment, the responsible veterinarian should subject the use of the veterinary medicinal product to the risk-benefit assessment.
If signs fail to improve within 7 days, treatment should be re-evaluated by the veterinarian.

- For alleviation of clinical signs associated with atopic dermatitis, repeat the treatment daily for at least 14 and up to 28 consecutive days.
An intermediary control by the veterinarian at day 14 should be made to decide if further treatment is needed. The dog should be re-evaluated regularly with regard to Hypothalamus-Pituitary-Adrenal Axis (HPA) suppression or skin atrophy, both being possibly asymptomatic. Any prolonged use of this product, to control atopy, should be based on the benefit risk assessment of the responsible veterinary surgeon. It should take place after a re-evaluation of the diagnosis and also a consideration of the multi-modal treatment plan in the individual animal.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Tolerance studies of multiple doses were assessed over a period of 14 days in healthy dogs using 3 and 5 times the recommended dosage corresponding to the two flanks, from the spine to the mammary chains including the shoulder and the thighs (1/3 of the dog's body surface area). These resulted in a reduced capacity for production of cortisol that is fully reversible within 7 to 9 weeks after the end of treatment.
In 12 dogs suffering from atopic dermatitis, after topical application once a day at the recommended therapeutic dosage for 28 to 70 (n=2) consecutive days, no noticeable effect on the systemic cortisol level was observed.

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: QD07AC16.

4.2 Pharmacodynamics

The veterinary medicinal product contains the active substance hydrocortisone aceponate.
Hydrocortisone aceponate is a dermocorticoid with a potent intrinsic glucocorticoid activity which means a relief of both inflammation and pruritus leading to a quick improvement of skin lesions observed in case of inflammatory and pruritic dermatosis. In case of atopic dermatitis, improvement will be slower.

4.3 Pharmacokinetics

Hydrocortisone aceponate belongs to the diesters class of the glucocorticosteroids.
The diesters are lipophilic components ensuring an enhanced penetration into the skin associated to a low plasma availability. Hydrocortisone aceponate thus accumulates in the dog's skin allowing local efficacy at low dosage. The diesters are transformed inside the skin structures. This transformation is responsible for the potency of the therapeutic class. In laboratory animals, hydrocortisone aceponate is eliminated the same way as hydrocortisone (other name for endogenous cortisol) through urine and faeces.
Topical application of diesters results in high therapeutic index: high local activity with reduced systemic secondary effects.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 6 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

A white high-density polyethylene (HDPE) bottle filled with 76 ml of solution, closed with either a polypropylene (PP) screw cap with Teflon coated polyethylene foam inlay or a spray nozzle with cap and low density polyethylene (LDPE)/PP dip tube.

Pack sizes:
Cardboard box with one bottle of 76 mL of solution.

5.5 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 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

NEXTMUNE ITALY S.R.L.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/24/306/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 08/04/2024.

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

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).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alcort 0.584 mg/ml cutaneous spray solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 0.584 mg hydrocortisone aceponate

3. PACKAGE SIZE

76 ml

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

NEXTMUNE ITALY S.R.L.

14. MARKETING AUTHORISATION NUMBERS

EU/2/24/306/001

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

HDPE Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alcort 0.584 mg/ml cutaneous spray solution

2. STATEMENT OF ACTIVE SUBSTANCES

Hydrocortisone aceponate 0.584 mg/ml

3. TARGET SPECIES

Dogs.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Not applicable.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months.

7. SPECIAL STORAGE PRECAUTIONS

Not applicable.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

NEXTMUNE ITALY S.R.L.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Alcort 0.584 mg/ml cutaneous spray solution for dogs

2. Composition

Each ml contains:

Active substance:
Hydrocortisone aceponate 0.584 mg/ml
Equivalent to 0.460 mg of hydrocortisone

Excipients:

Qualitative composition of excipients and other constituents
Propylene glycol methyl ether

3. Target species

Dogs.

4. Indications for use

For symptomatic treatment of inflammatory and pruritic dermatoses in dogs.
For alleviation of clinical signs associated with atopic dermatitis in dogs.

5. Contraindications

Do not use on cutaneous ulcers.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special precautions for safe use in the target species:

Clinical signs of atopic dermatitis such as pruritus and skin inflammation are not specific for this disease and therefore other causes of dermatitis such as ectoparasitic infestations and infections which cause dermatological signs should be ruled out before treatment is started, and underlying causes should be investigated.
In the case of concurrent microbial disease or parasitic infestation, the dog should receive appropriate treatment for such condition.
In the absence of specific information, the use in animal suffering from Cushing's syndrome shall be based on the risk-benefit assessment.
Since glucocorticosteroids are known to slow growth, use in young animals (under 7 months of age) shall be based on the risk-benefit assessment and subject to regular clinical evaluations.

Total body surface treated should not exceed approximately 1/3 of the dog's surface corresponding for example to a treatment of two flanks from the spine to the mammary chains including the shoulders and the thighs. See also section "Overdose". Otherwise, use only according to the risk-benefit assessment of the responsible veterinary surgeon and subject the dog to regular clinical evaluations as further described in section "Dosage for each species, route(s) and method of administration".

Care should be taken to avoid spraying into the eyes of the animal.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The active substance is potentially pharmacologically active at high doses of exposure.
The formulation may cause eye irritation following accidental ocular contact.
The formulation is flammable.

Wash hands after use. Avoid contact with eyes.
To avoid skin contact, recently treated animals should not be handled until the application site is dry.
To avoid inhalation of the product, apply the spray in a well-ventilated area.

Do not spray on naked flame or any incandescent material.
Do not smoke while handling the veterinary medicinal product.
Replace the bottle in the outer carton and in a safe place out of the sight and the reach of children immediately after use.

In case of accidental skin contact, avoid hand-to-mouth contact and wash the exposed area immediately with water.
In case of accidental eye contact, rinse with abundant quantities of water.
If eye irritation persists, seek medical advice.
In case of accidental ingestion, especially by children, seek medical advice immediately and show the package leaflet or the label to the physician.

Other precautions:

The solvent in this product may stain certain materials including painted, varnished or other household surfaces or furnishings. Allow the application site to dry before permitting contact with such materials.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Systemic absorption of hydrocortisone aceponate being negligible, it is unlikely for teratogenic, foetotoxic, maternotoxic effects to happen at the recommended dosage in dogs.
Use only according to the benefit-risk assessment by the responsible veterinarian.

Fertility:

Use only according to the benefit-risk assessment by the responsible veterinarian.

Interactions with other medicinal products and other forms of interaction:

No data available.
In the absence of information, it is recommended not to apply other topical preparations simultaneously on the same lesions.

Overdose:

Tolerance studies of multiple doses were assessed over a period of 14 days in healthy dogs using 3 and 5 times the recommended dosage corresponding to the two flanks, from the spine to the mammary

chains including the shoulder and the thighs (1/3 of the dog's body surface area). These resulted in a reduced capacity for production of cortisol that is fully reversible within 7 to 9 weeks after the end of treatment.
In 12 dogs suffering from atopic dermatitis, after topical application once a day at the recommended therapeutic dosage for 28 to 70 (n=2) consecutive days, no noticeable effect on the systemic cortisol level was observed.

Major incompatibilities:

Do not mix with any other veterinary medicinal products.

7. Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports): transient local reactions at the application site (erythema (redness) and/or pruritus (itching))

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

For cutaneous use.
Before administration, screw the pump spray on the bottle.
The veterinary medicinal product is then applied by activating the pump spray, from a distance of about 10 cm of the area to be treated.
The recommended dosage is 1.52 µg of hydrocortisone aceponate/cm^2 of affected skin per day. This dosage can be achieved with two pump spray activations over a surface to be treated equivalent to a square of 10 cm x 10 cm.

- For treatment of inflammatory and pruritic dermatoses, repeat the treatment daily for 7 consecutive days.

In case of conditions requiring an extended treatment, the responsible veterinarian should subject the use of the veterinary medicinal product to the risk-benefit assessment.
If signs fail to improve within 7 days, treatment should be re-evaluated by the veterinarian.

- For alleviation of clinical signs associated with atopic dermatitis, repeat the treatment daily for at least 14 and up to 28 consecutive days.

An intermediary control by the veterinarian at day 14 should be made to decide if further treatment is needed. The dog should be re-evaluated regularly with regard to Hypothalamus-Pituitary-Adrenal Axis (HPA) suppression or skin atrophy, both being possibly asymptomatic.
Any prolonged use of this product, to control atopy, should be based on the benefit risk assessment of the responsible veterinary surgeon. It should take place after a re-evaluation of the diagnosis and also a consideration of the multi-modal treatment plan in the individual animal.

9. Advice on correct administration

Presented as a volatile spray, this veterinary medicinal product does not require any massage.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 6 months.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/24/306/001

15. Date on which the package leaflet was last revised

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

NEXTMUNE ITALY S.R.L.
Via G.B. Benzoni 50
26020 Palazzo Pignano (CR)
Phone +39 0373 982024
Italia

Manufacturer responsible for batch release:

Floris Veterinaire Produkten BV
Kempenlandstraat 33
5262GK Vught
The Netherlands

17. Other information

Hydrocortisone aceponate administered topically accumulates and is metabolised in skin, as suggested by radioactivity distribution studies and pharmacokinetic data. This results in minimal amounts to reach the blood stream. This particularity will increase the ratio between the desired local anti-inflammatory effect in the skin and the undesirable systemic effects.

Hydrocortisone aceponate applications on the skin lesions provide rapid reduction of the skin redness, irritation and scratching while minimising the general effects.

Pack sizes:
A white high-density polyethylene (HDPE) bottle filled with 76 ml of solution, closed with either a polypropylene (PP) screw cap with Teflon coated polyethylene foam inlay or a spray nozzle with cap and low density polyethylene (LDPE)/PP dip tube.