SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Isaderm vet gel for dogs (SE, IT)
Isaderm gel for dogs (EL, ES, PT)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substances:
Fusidic acid 5 mg
Betamethasone 1 mg (as valerate)

Excipients:

Qualitative composition of excipients and other constituents
Methyl parahydroxybensoate (E218)
Propyl parahydroxybensoate (E216)
Carbomer
Polysorbate 80
Dimethicone
Sodium hydroxide
Purified water

White gel.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For the topical treatment of localised, mild or moderate acute moist dermatitis ("hot spots").
Considerations should be given to official guidance on the appropriate use of antibacterial agents.

3.3 Contraindications

Do not use in case of hypersensitivity to the active substances or to any of the excipients.
Should not be used for superficial pyoderma such as impetigo, follicullitis and acne as well as for deep pyoderma as glucocorticoids are contraindicated in these conditions.
Should not be used for fungal infection or in Cushings disease.
Do not use in dogs with extensive lesions, infected lesions of fungal, viral or parasitic origin or in dogs with ulcerated lesions.

3.4 Special warnings

Please see section 3.6

3.5 Special precautions for use

Special precautions for safe use in the target species:

Betamethasone valerate is absorbed percutaneously and may cause temporary suppression of adrenal function. Prolonged treatment or treatment of large surface areas as well as application under occlusive
dressing and in cases where the dog can lick the gel, the risk for systemic effects must be taken into consideration. The product should be used with caution in small dogs and puppies (less than 12 weeks). If the dog scratches or licks the treated lesions a protective collar could be used.
2
The glycaemic control of diabetic patients should be monitored with care during treatment with the product.

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

Corticosteroids, especially with frequent and extensive use (during a period), may cause atrophy of the skin and can be absorbed and may then have harmful effects. Fusidic acid may select for resistant stains of human skin Staphylococci and in rare cases hypersensitivity reactions may occur. In order to avoid contact with the product when applying the gel, the person administrating the drug should wear protective gloves. Contact with eyes should be avoided.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Skin thinning[a] Hypersensitivity reaction Delayed healing[b]
Undetermined frequency (cannot be estimated from the available data)	Capillary fragility[a] Adrenal gland disorder[c]

[a] With locally applied steroids.

[b] Of wounds.

[c] Topically-applied betamethasone is absorbed percutaneously and may cause temporary suppression of adrenal function if the product is used over large surface areas or for a prolonged period.

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

The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

Pregnancy and lactation:

Do not use during pregnancy and lactation.
Betamethasone is known to be teratogenic in laboratory species.

3.8 Interaction with other medicinal products and other forms of interaction

Interaction studies have not been performed. Do not apply other topical preparations concomitantly to the same lesions.

3.9 Administration routes and dosage

Cutaneous use.

Clean the affected areas and clip the hair covering the lesions before application. The gel should be applied as a thin film to the surface to the lesion, twice daily for a minimum period of 5 days. Treatment should continue for 2 days after the lesion has resolved. The treatment period should not exceed 7 days.
If there is no response within three days, or if the condition deteriorates, the diagnosis should be reevaluated.

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

Overdosing i.e. application rate of more than twice daily or an extension of the duration of treatment increases the risk of corticosteroid side effects, particularly when administered to extensive lesions.

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

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :
QD07CC01

4.2 Pharmacodynamics

Betamethasone valerate is a glucocorticoid with anti-inflammatory and antipruritic effects.
Fusidic acid is an antibiotic active primarily against Staphylococci. Fusidic acid is also active against Streptococci.

4.3 Pharmacokinetics

In vitro data obtained from a study on dog skin indicate that 17% of the applied dose of betamethasone and 2.5% of the applied dose of fusidic acid are absorbed over 48 hours after the administration of Fuciderm to the skin.
Absorption after administration to inflamed skin is likely to be greater.
In man absorbed fractions of the active ingredients are widely distributed throughout the body and have a high level of plasma protein binding. Both active ingredients are extensively metabolised in the liver. Fusidic acid is excreted almost entirely in the bile, mostly as inactive metabolites.
Betamethasone-17-valerte is excreted primarily as the metabolised water-soluble ester in the urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

5.3 Special precautions for storage

Do not refrigerate or freeze.

5.4 Nature and composition of immediate packaging

Aluminium tubes of 15g, 10x15 g and 30g
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

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

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

2025-09-03

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).