1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Isaderm 5 mg/g + 1 mg/g gel for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:
Active substances:
Fusidic acid 5 mg
Betamethasone (as betamethasone valerate) 1 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate (E218)	2.7 mg
Propyl parahydroxybenzoate	0.3 mg
Carbomer (E1210)	
Polysorbate 80 (E433)	
Dimeticone	
Sodium hydroxide (for pH adjustment) (E524)	
Purified water	

White to off-white, opaque gel.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For the topical treatment of surface pyoderma such as acute moist dermatitis (‘hot spots’) and intertrigo (skin fold dermatitis).

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use for the treatment of deep pyoderma.
Do not use in pyotraumatic furunculosis and pyotraumatic folliculitis with ‘satellite’ lesions of papules or pustules.
Do not use where fungal or viral infection is present.
Do not apply to the eye.
Do not use over large surface areas or for prolonged treatment.
See section 3.7.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Official, national and regional antimicrobial policies should be taken into account when the product is used.
Betamethasone valerate can be absorbed percutaneously and may cause temporary suppression of adrenal function.
The dog should be prevented from licking treated lesions and so ingesting the product. Where there is a risk of self-trauma or a risk of accidental transfer to the eye, for example, application of the product on the forelimb, preventative measures such as the use of an Elizabethan collar should be considered.
Pyoderma is often secondary in nature. The underlying cause should be identified and treated.
It is recommended that use of the product should be based on bacteriological sampling and susceptibility testing. If this is not possible, therapy should be based on epidemiological information about susceptibility of the target bacteria. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to fusidic acid.
The safety of the combination has not been assessed in puppies of less than 7 months.

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

Corticosteroids may produce irreversible effects in the skin; they can be absorbed and may have harmful effects, especially with frequent and extensive contact or in pregnancy. Pregnant women should take special care to avoid accidental exposure. Personal protective equipment consisting of single-use disposable gloves should be worn when handling the veterinary medicinal product.
Wash hands after having applied the product.
Care should be taken to avoid accidental ingestion by a child. In the case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
People with known hypersensitivity to the active ingredients or to any of the excipients should avoid contact with the veterinary medicinal product.

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):	Systemic disorder[1] (e.g. Skin thinning, Delayed healing Adrenal gland disorder[2]) Hypersensitivity reaction[3] Application site pigmentation disorder[4]

[1] May be triggered by prolonged and intensive use of topical corticosteroid preparations or treatment of a large cutaneous surface (>10%).

[2] Suppression of adrenal function.

[3] Discontinue use if develops.

[4] Depigmentation of the skin.

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 and lactation.

Pregnancy and lactation:

Laboratory studies showed that topical application of betamethasone in pregnant females may lead to malformations in neonates. The use is not recommended during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Cutaneous use.
First, the hairs covering the lesions should be gently clipped. The affected area should then be thoroughly cleaned with an antiseptic wash before application of the gel. The amount applied should cover the affected area in a thin layer. Apply approximately 0.5 cm length of gel per 8 cm^2 of lesion, twice daily, for a minimum period of 5 days. Treatment should continue for 48 hours after the lesion has resolved. The treatment period should not exceed 7 days. If there is no response within three days, or the condition deteriorates, the diagnosis should be re-evaluated.

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

For possible signs see 3.6 above.

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 :
QD07 CC01

4.2 Pharmacodynamics

Betamethasone valerate is a potent corticosteroid that possesses anti-inflammatory and anti-pruritic properties.
Fusidic acid has a steroidal structure but does not possess any steroid-like effects. It belongs to the class of antibiotics called Fusidanes. Fusidic acid acts by prohibiting the protein synthesis of bacteria when it binds to elongation factor G (required for translocation on the bacterial ribosome after peptide bond formation during protein synthesis).
Its action is largely bacteriostatic, but at high concentrations (2 to 32-fold higher than the MIC) the effect may be bactericidal. Fusidic acid has activity against Gram-positive bacteria, namely *Staphylococcus* spp. (particularly *S.pseudintermedius*) including penicillinase producing species. It is also active against streptococci.

Pathogenic bacteria	Fusidic acid Sensitive / Resistant	Fusidic acid MIC
Gram-positive bacteria - *Staphylococcus pseudintermedius* - *Streptococcus* spp. - *Corynebacteria* spp.	 Sensitive Sensitive Sensitive	 MIC_{90}≅ 0.25-4 µg/ml MIC_{90}≅ 8-16 µg/ml MIC_{90} ≅ 0.04 – 12.5 µg/ml
Gram-negative bacteria - *Pseudomonas* spp. - *E.coli*	 Resistant Resistant	 >128 µg/ml >128 µg/ml

Data based on studies conducted mainly in Europe but also in North America between 2002 and 2011.

Two major mechanisms of resistance to fusidic acid have been reported in S. aureus – the alteration of the drug target site which is due to chromosomal mutations in FusA (encoding elongation factor EF-G) or FusE encoding ribosome protein L6, and the protection of the drug target site by FusB family proteins, including fusB, fusC, and fusD. The fusB determinant originally was found on the plasmid in S. aureus but has also been found on a transposon-like element or in a staphylococcal pathogenicity. No cross-resistance between fusidic acid and other antibiotics that are in clinical use has been identified.

4.3 Pharmacokinetics

In vitro data obtained from a study on dog skin indicates 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 the product to the skin. Absorption after administration to inflamed skin is likely to be greater.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

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 weeks.

5.3 Special precautions for storage

Do not store above 30 °C.
Do not refrigerate or freeze.
Keep the tube in the outer carton.

5.4 Nature and composition of immediate packaging

Internally lacquered aluminium tube closed with a white HDPE screw cap.

Pack sizes:
Cardboard box with 1 x 15 g
Cardboard box with 1 x 30 g

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

Dechra Veterinary Products A/S

7. MARKETING AUTHORISATION NUMBER(S)

VPA10803/006/001

8. DATE OF FIRST AUTHORISATION

14/03/2014

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

15/09/2025

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).