

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 cm² 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 - <i>Staphylococcus pseudintermedius</i> - <i>Streptococcus</i> spp. - <i>Corynebacteria</i> 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 - <i>Pseudomonas</i> spp. - <i>E.coli</i>	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

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON 15 g and 30 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Isaderm 5 mg/g + 1 mg/g gel

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:

Fusidic acid	5 mg	
Betamethasone (as betamethasone valerate)		1 mg

3. PACKAGE SIZE

15 g
30 g

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 6 weeks, by...

9. SPECIAL STORAGE PRECAUTIONS

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

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

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Tube 15 g and 30 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Isaderm

15 g

30 g

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Fusidic acid 5 mg/g

Betamethasone (as betamethasone valerate) 1 mg/g

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each g contains:

Active substances:

Fusidic acid	5 mg
Betamethasone (as betamethasone valerate)	1 mg

Excipients:

Methyl parahydroxybenzoate (E218)	2.7 mg
Propyl parahydroxybenzoate	0.3 mg

White to off-white, opaque gel.

3. Target species

Dogs.

4. Indications for use

For the topical treatment of certain skin diseases such as acute moist dermatitis ('hot spots') and intertrigo (skin fold dermatitis).

5. 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 'Pregnancy and lactation'.

6. Special warnings

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, 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 package leaflet text 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 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.

Pregnancy and lactation:

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

Overdose:

For possible signs see section ‘Adverse events’.

7. 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 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 or its local representative 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

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 daily 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 cm² 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.

9. Advice on correct administration

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 30 °C.

Do not refrigerate or freeze.

Keep the tube in the outer carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and tube label after Exp. The expiry date refers to the last day of that month

Shelf life after first opening the immediate packaging: 6 weeks.

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

Pack sizes:

Cardboard box with 1 x 15 g.

Cardboard box with 1 x 30 g.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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

16. Contact details

Marketing authorisation holder:

Manufacturer responsible for batch release:

Genera Inc.
Svetonedeljska cesta 2
Kalinovica
10436 Rakov Potok
Croatia

Dales Pharmaceuticals Limited
Snaygill Industrial Estate Keighley Road
Skipton North Yorkshire, BD23 2RW
United Kingdom

Local representatives and contact details to report suspected adverse events:

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