PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Isaderm vet gel for dogs

2. Composition

Each g contains:
Active substance: Fusidic acid 5 mg, Betamethasone 1 mg (as valerate)

White gel.

3. Target species

Dogs.

4. Indications for use

Fusidic acid is an antibiotic. Betamethasone valerate is a glucocorticoid with anti-inflammatory and antiprutic effects.
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.

5. Contraindications

Do not use in case of hypersensitivity to the active substances or to any of the other ingredients.
Should not be used for deeper infections of the skin such as pustules (impetigo), infection of the hair follicles (follicullitis) and acne as well as for very deep infections of the skin (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.

6. Special warnings

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.
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.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Do not use during pregnancy and lactation.
Betamethasone is known to be teratogenic in laboratory species.

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.

Overdose:
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.

7. 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 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.

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.
If other instructions have been given by your veterinarian surgeon, those instructions should be followed.

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 refrigerate or freeze.

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

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

Aluminium tubes of 15g, 10x15g and 30g.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

2025-09-03

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 events:

Manufacturer responsible for batch release:
Genera Inc.
Svetonedeljska cesta 2
Kalinovica
10436 Rakov Potok
Croatia

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.