1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trigoderm 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 the valerate ester) 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**
Methylparahydroxybenzoate (E 218)	2.7 mg
Propylparahydroxybenzoate (E 216)	0.3 mg
Carbomer	
Polysorbate 80	
Dimeticone	
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 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. Discontinue use if hypersensitivity develops to the veterinary medicinal product.
Do not use for the treatment of deep pyoderma.
Do not use where fungal infection is present.
Do not apply to the eye.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Betamethasone valerate can be absorbed percutaneously and may cause temporary suppression of adrenal function. Prolonged treatment or the treatment of large surface areas should be avoided.
The dog should be prevented from licking treated lesions and so ingesting the veterinary medicinal product. Where there is a risk of self-trauma, preventative measures such as the use of an Elizabethan collar should be considered.

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.
Personal protective equipment consisting of single-use disposable gloves should be worn when handling the veterinary medicinal product.
Wash hands after applying 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):	Cushings disease[a], Adrenal gland disorder[b] Skin thinning[c] Delayed healing[d] Immunosuppression[e] Hepatomegaly, Elevated liver enzymes Gastrointestinal ulceration[f]

[a] May cause Cushingoid symptoms involving significant alteration of fat, carbohydrate, protein and mineral metabolism e.g. redistribution of body fat, muscle weakness and wastage and osteoporosis may result.

[b] During therapy effective doses suppress the Hypothalamo-pituitreal-adrenal axis. Following cessation of treatment, symptoms of adrenal insufficiency can arise and this may render the animal unable to deal adequately with stressful situations.

[c] With locally applied steroids.

[d] Of wounds.

[e] Weaken resistance to or exacerbate existing infections. In the presence of viral infections, steroids may worsen or hasten the progress of the disease.

[f] Has been reported in animals treated with corticosteroids and gastrointestinal ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.

Anti-inflammatory corticosteroids, such as betamethasone valerate, are known to exert a wide range of side-effects. Whilst single high doses are generally well tolerated, they may induce severe side-effects in long term use and when esters possessing a long duration of action are administered. Dosage in medium to long term use should therefore generally be kept to the minimum necessary to control symptoms.

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:
Corticosteroids are not recommended for use on pregnant animals. Administration during pregnancy may cause abortion or early parturition. Do not use during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Cutaneous use.

Apply a quantity of the gel to the affected area, 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 possesses anti-inflammatory and anti-pruritic properties.

Fusidic acid is an antibiotic which is active against Staphylococcus, in particular *S. intermedius*. It 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 Trigoderm 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

None known.

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.
Keep the tube in the outer carton.

5.4 Nature and composition of immediate packaging

Tubes of 5 g, 15 g or 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)

VPA10803/002/001

8. DATE OF FIRST AUTHORISATION

19/03/2004

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

30/07/2026

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).