SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fuciderm gel for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

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

Excipients:
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

White gel

4. CLINICAL PARTICULARS

4.1 Target species

Dog

4.2 Indications for use, specifying the 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.

4.3 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, folliculitis 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.

4.4 Special warnings
Please see section 4.6

4.5 Special precautions for use

Special precautions for use in animals
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.

4.6 Adverse reactions (frequency and seriousness)

Locally applied steroids may cause thinning of the skin and capillary fragility. Hypersensitivity is a possible adverse effect from treatment with Fuciderm.

Corticosteroids may delay wound healing. 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.

4.7 Use during pregnancy and lactation

Betamethasone is known to be teratogenic in laboratory species. The safety of the product has not been established in pregnant and lactating bitches; consequently the use of the product is contra-indicated in pregnant and lactating bitches.

4.8 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.

4.9 Amounts to be administered and administration route

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 re-evaluated.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Corticosteroids, combinations with antibiotics
ATC vet code: QD07CC01

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybensoate (E218)
Propyl parahydroxybensoate (E216)
Carbomer
Polysorbate 80
Dimethicone
Sodium hydroxide
Purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

6.4. Special precautions for storage

Do not refrigerate or freeze.

6.5 Nature and composition of immediate packaging

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

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Dechra Veterinary Products A/S
Mekuvej 9
7171 Uldum

Denmark

8. MARKETING AUTHORISATION NUMBER(S)

13281

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14 November 1997
Date of last renewal: 14 November 2007

10 DATE OF REVISION OF THE TEXT

2010-08-20

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.