PACKAGE LEAFLET
Fuciderm gel for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Dechra Veterinary Products A/S Mekuvej 9
7171 Uldum
Denmark

Manufacturer for the batch release:
Dales Pharmaceuticals
Snaygill Industrial Estate
Keighley Road
Skipton, North Yorkshire
BD23 2RW, United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fuciderm gel for dogs
Fusidic acid 0.5% and Betamethasone 0.1% (as valerate)

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

1 g Fuciderm gel contains:
Active substance: Fusidic acid 5 mg, Betamethasone 1 mg (as valerate)
Other ingredients: Methyl parahydroxybensoate (E218), Propyl parahydroxybensoate (E216), Carbomer, Polysorbate 80, Dimethicone, Sodium hydroxide and Purified water.

4. INDICATION(S)

Fusidic acid is an abtibiotic. 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 (folliculitis) 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. ADVERSE REACTIONS

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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dog

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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

9. ADVICE ON CORRECT ADMINISTRATION

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10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Do not refrigerate or freeze.

Do not use after the expiry date stated on the carton

12. SPECIAL WARNING(S)

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.

Use during pregnancy and lactation
The safety of the product has not been established in pregnant and lactating bitches; consequently the product must not be used in pregnant and lactating bitches.

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 (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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

2010-08-20

15. OTHER INFORMATION

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

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

To be completed nationally