SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trigoderm Gel 0.5 % w/w Fusidic acid, 0.1 % w/w Betamethasone

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances:
Fusidic acid 0.5 % w/w
Betamethasone 0.1 % w/w (as the valerate ester)

Preservatives:
Methylparahydroxybenzoate (E 218) 0.27 % w/w
Propylparahydroxybenzoate (E 216) 0.03 % w/w

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 surface pyoderma in the dog such as acute moist dermatitis ('hot spots') and intertrigo (skin fold dermatitis).

4.3 Contraindications

Do not use in animals with hypersensitivity to any of the components. Discontinue use if hypersensitivity develops to the product.

Do not use for the treatment of deep pyoderma as glucocorticoids are contra-indicated in this condition.

Do not use where fungal infection is present.

Do not apply to the eye.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

i) Special precautions for use in animals

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.

Avoid eye contact.

ii) 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. Always wear single-use disposable gloves when applying this product to animals.

Wash hands after applying the product.

4.6 Adverse reactions (frequency and seriousness)

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.

Steroids themselves, during treatment, 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. 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.

Locally applied steroids may cause thinning of the skin.

Corticosteroids may delay wound healing and the immunosupressant actions may weaken resistance to or exacerbate existing infections. In the presence of viral infections, steroids may worsen or hasten the progress of the disease.

Gastrointestinal ulceration 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. Steroids may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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.

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

For possible signs see 4.6 above.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

ATCvet code: QD07 CC01

5.1 Pharmacodynamic properties

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.

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 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer
Polysorbate 80
Methylparahydroxybenzoate (E 218)
Propylparahydroxybenzoate (E 216)
Dimeticone
Sodium hydroxide
Purified water

6.2 Incompatibilities

None known.

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

Tubes of 5 g, 15 g or 30 g.

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

Vm 24883/4001

9. DATE OF FIRST AUTHORISATION

Date: 07 March 1995

10. DATE OF REVISION OF THE TEXT

Date: December 2014

APPROVED T. NASH **31/12/14**