Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Betafuse 1 mg/g + 5 mg/g gel for dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substances:

Betamethasone (as betamethasone valerate)	1 mg
Fusidic acid (as fusidic acid hemihydrate)	5 mg

Excipients:

Sodium methyl parahydroxybenzoate (E219)	3.1 mg
Sodium propyl parahydroxybenzoate	0.337 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel.
An off-white to white gel.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the target species

For the treatment of acute surface pyoderma, such as acute moist dermatitis ('hot spots') and intertrigo (skin fold dermatitis), caused by Gram-positive bacteria sensitive to fusidic acid.

4.3 Contraindications

Do not use in cases of deep pyoderma.
Do not use in cases of pyotraumatic furunculosis and pyotraumatic folliculitis with ‘satellite’ lesions of papules or pustules.
Do not use where fungal or viral infection, or demodicosis is present.
Do not apply to the eye.
Do not use over large surface areas or for prolonged treatment.
Do not use in cases of impetigo or acne.
Do not use in cases of unstabilised or untreated Cushing’s syndrome or diabetes mellitus.
Do not use in cases of pancreatitis.
Do not use in cases of gastrointestinal ulcers.
Do not use in cases of known hypersensitivity to the active substances or to any of the excipients.
Do not use in the case of resistance to fusidic acid.
See section 4.7.

4.4 Special warnings for each target species

Pyoderma is often secondary in nature. The underlying cause should be identified and treated.

4.5 Special precautions for use

Special precautions for use in animals
Official, national and regional antimicrobial policies should be taken into account when the product is used.
It is recommended that use of the product should be based on bacteriological sampling and susceptibility testing. If this is not possible, therapy should be based on epidemiological information about susceptibility of the target bacteria. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to fusidic acid.
Use of the product in association with occlusive bandages or dressings should be avoided.
Betamethasone valerate can be absorbed percutaneously and may cause temporary suppression of adrenal function.
In dogs with treated and stabilised Cushing's syndrome, only use the product after careful consideration of the benefit risk balance by the responsible veterinary surgeon.
Avoid eye contact. In case of accidental contact, rinse thoroughly with water.
The dog should be prevented from licking treated lesions and so ingesting the product.
Where there is a risk of self-trauma or a risk of accidental transfer to the eye, for example, application of the product on the forelimb, preventative measures such as the use of a protective collar should be considered.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known hypersensitivity to the active ingredients or to any of the excipients should avoid contact with the veterinary medicinal product.
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. Pregnant women should take special care to avoid accidental exposure.
Always wear single-use impermeable gloves when applying this product to animals.
Wash hands after having applied the product.
Care should be taken to avoid contact with treated areas of the animal, for the duration of the treatment period.
Care should be taken to avoid accidental ingestion by a child. In the case of accidental ingestion, seek medical advice immediately and show the package leaflet to the physician.

4.6 Adverse reactions (frequency and seriousness)

Prolonged and intensive use of topical corticosteroid preparations or treatment of a large cutaneous surface (>10%) is known to trigger local or systemic effects including suppression of adrenal function, thinning of the epidermis and delayed healing.
Locally applied steroids may cause depigmentation of the skin.
Discontinue use if hypersensitivity develops to the product.

4.7 Use during pregnancy, lactation or lay

The use of the product during pregnancy and lactation is not recommended. The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Laboratory studies have demonstrated that topical application of betamethasone in pregnant females may lead to malformations in neonates. Small amounts of betamethasone can pass the blood-milk-barrier.

4.8 Interaction with other medicinal products and other forms of interactions

Concurrent treatment with steroids and NSAIDs may increase the risk for the development of gastrointestinal ulcers.

4.9 Amounts to be administered and administration route

Cutaneous use.
First, the hairs covering the lesions should be gently clipped. The affected area should then be thoroughly cleaned with an antiseptic wash before daily application of the gel. The amount applied should cover the affected area in a thin layer. Apply approximately 0.5 cm length of gel per 8 cm^2 of lesion, 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

No other symptoms than those mentioned in section 4.6 are expected.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Corticosteroids, combinations with antibiotics.
ATCvet code: QD07 CC01

5.1 Pharmacodynamic properties

Betamethasone valerate is a potent synthetic corticosteroid (dexamethasone-analogue) with anti-inflammatory and anti-pruritic activity when applied topically as well as mild mineralocorticoid properties.

Fusidic acid hemihydrate has a steroidal structure but does not possess any steroid-like effects. It belongs to the class of antibiotics called Fusidanes. Fusidic acid hemihydrate acts by prohibiting the protein synthesis of bacteria when it binds to elongation factor G (required for translocation on the bacterial ribosome after peptide bond formation during protein synthesis).
Its action is largely bacteriostatic, but at high concentrations (2 to 32-fold higher than the MIC) the effect may be bactericidal.
Fusidic acid hemihydrate has activity against Gram-positive bacteria, namely *Staphylococcus* spp. (particularly *S. pseudintermedius*) including penicillinase producing species. It is also active against streptococci.

Pathogenic Bacteria	**Fusidic Acid Sensitive / Resistant**	**Fusidic Acid MIC**
Gram-positive bacteria		
- *Staphylococcus pseudintermedius*	Sensitive	MIC_{90} 0.25 - 4 µg/ml
- *Streptococcus* spp.	Sensitive	MIC_{90} 8 - 16 µg/ml
- *Corynebacteria* spp.	Sensitive	MIC_{90} 0.04 - 12.5 µg/ml
Gram-negative bacteria		
- *Pseudomonas* spp.	Resistant	>128 µg/ml
- *E.coli*	Resistant	>128 µg/ml

Data based on studies conducted mainly in Europe but also in North America between 2002 and 2011.

Two major mechanisms of resistance to fusidic acid hemihydrate have been reported in *S. aureus* – the alteration of the drug target site which is due to chromosomal mutations in FusA (encoding elongation factor EF-G) or FusE encoding ribosome protein L6, and the protection of the drug target site by FusB family proteins, including fusB, fusC, and fusD. The fusB determinant originally was found on the plasmid in S. aureus but has also been found on a transposon-like element or in a staphylococcal pathogenicity island.
No cross-resistance between fusidic acid hemihydrate and other antibiotics that are in clinical use has been identified.

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 hemihydrate are absorbed over 48 hours after the administration of the product to the skin. Betamethasone valerate is absorbed after topical application. Absorption after administration to inflamed skin is likely to be greater. Following systemic absorption betamethasone can cross the blood-brain barrier, the blood-placenta barrier and, in small amounts, may pass into the milk of lactating animals.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium methyl parahydroxybenzoate (E219)
Sodium propyl parahydroxybenzoate
Carbomer
Polysorbate 80
Dimeticone
Hydrochloric acid (for pH adjustment)

Sodium hydroxide (for pH adjustment)
Purified water

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the container: 8 weeks.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

White polyethylene coated aluminium tubes of 15 g or 30 g closed with a polypropylene cap.

Not all pack sizes may be marketed.

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

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

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/129/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16 September 2016
Date of last renewal: 30 July 2021

10 DATE OF REVISION OF THE TEXT

July 2021