

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**  
**{15 g and 30 g Carton}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Betafuse 1 mg/g + 5 mg/g gel

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each g contains:

Active substances:

Betamethasone (as betamethasone valerate) 1 mg

Fusidic acid (as fusidic acid hemihydrate) 5 mg

**3. PACKAGE SIZE**

15g

30 g

**4. TARGET SPECIES**

Dogs

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Cutaneous use.

Read the package leaflet before use.

**7. WITHDRAWAL PERIODS**

Withdrawal period: Not Applicable

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened, use within 8 weeks.

Once opened, use by .....

**9. SPECIAL STORAGE PRECAUTIONS**

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Pregnant women should take special care to avoid accidental exposure.

Always wear single-use impermeable gloves when applying this product to animals.

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

Norbrook Laboratories Limited

**14. MARKETING AUTHORISATION NUMBER**

Vm 02000/4404

**15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**  
**15 g and 30 g Tube Label**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Betafuse 1 mg/g + 5 mg/g gel

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each g contains:

Active substances:

Betamethasone (as betamethasone valerate) 1 mg

Fusidic acid (as fusidic acid hemihydrate) 5 mg

**3. TARGET SPECIES**

Dogs

**4. ROUTES OF ADMINISTRATION**

Read the package leaflet before use.

**5. WITHDRAWAL PERIODS**

Withdrawal periods: Not applicable

**6. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use within 8 weeks.

Once opened use by ...

**7. SPECIAL STORAGE PRECAUTIONS**

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

Norbrook Laboratories Limited

**9. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

**PACKAGE LEAFLET**

**1. Name of the veterinary medicinal product**

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

**2. 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

An off-white to white gel.

**3. Target species**

Dogs

**4. Indications for use**

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.

**5. 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 unbalanced 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 hypersensitivity to the active substances or to any of the excipients.

Do not use in the case of resistance to fusidic acid.  
See section 6 'Special warning', subsection 'Pregnancy and lactation'.

## **6. Special warnings**

### Special warnings:

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

### Special precautions for safe use in the target species:

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 this package leaflet may increase the prevalence of bacteria resistant to fusidic acid.

The amount of product applied should not exceed the recommended dosage.

Use of the product in association with occlusive bandages or dressings should be avoided.

Betamethasone valerate can be absorbed through the skin 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 fusidic acid, betamethasone 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.

Personal protective clothing consisting of single-use impermeable gloves must be worn 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 or the label to the physician.

### Pregnancy and lactation:

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 new-borns. Small amounts of betamethasone can pass the blood-milk-barrier.

Interaction with other medicinal products and other forms of interaction:

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

Overdose:

For possible signs see the “Adverse events” section of this package leaflet.

## 7. Adverse events

Target species: Dogs

Undetermined frequency	Systemic disorder (e.g. suppression of adrenal function <sup>1</sup> , thinning of the epidermis <sup>1</sup> , delayed healing <sup>1</sup> ). Pigmentation disorder (e.g. depigmentation of the skin <sup>2</sup> ). Hypersensitivity <sup>3</sup> .
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<sup>1</sup> May be triggered by prolonged and intensive use of topical corticosteroid preparations or treatment of a large cutaneous surface (>10%).

<sup>2</sup> May be caused by locally applied steroids.

<sup>3</sup> If develops, discontinue use.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

## 8. Dosage for each species, routes and method of administration

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<sup>2</sup> 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.

## **9. Advice on correct administration**

Follow your veterinary surgeon's instructions about when and how to use this product. Read the package leaflet carefully.

## **10. Withdrawal periods**

Not Applicable

## **11. Special storage precautions**

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions. Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month. Shelf life after first opening the immediate packaging: 8 weeks.

## **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

Vm 02000/4404

Pack sizes:

Carton with one tube containing 15 g gel.

Carton with one tube containing 30 g gel

Not all pack sizes may be marketed.

### **15. PID link (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

### **16. Contact details**

Marketing authorisation holder and contact details to report suspected adverse reactions:

Norbrook Laboratories Limited  
Station Works  
Camlough Road  
Newry  
County Down  
Northern Ireland  
BT35 6JP  
Tel: +44 (0)28 3026 4435  
E-mail: [phvdept@norbrook.co.uk](mailto:phvdept@norbrook.co.uk)

Manufacturer responsible for batch release:

Norbrook Laboratories Limited,  
Station Works  
Camlough Road,  
Newry,  
County Down,  
Northern Ireland  
BT35 6JP  
Tel: +44 (0)28 3026 4435  
E-mail: [phvdept@norbrook.co.uk](mailto:phvdept@norbrook.co.uk)

### **17. Other information**

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*Gavin Hall*  
Approved: 17 February 2025