ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

{15 g and 30 g Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:

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

3. PHARMACEUTICAL FORM

Gel

4. PACKAGE SIZE

15 g
30 g

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

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.

10. EXPIRY DATE

EXP {dd/mm/yyyy}

Once opened, use within 8 weeks.
Use by ……

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4404

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{15 g and 30 g Tube Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each g contains:
Betamethasone (as betamethasone valerate) 1 mg
Fusidic acid (as fusidic acid hemihydrate) 5 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

15 g
30 g

4. ROUTE(S) OF ADMINISTRATION

Cutaneous use.

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Lot: See base of tube.

{xxxx-xxx}

7. EXPIRY DATE

EXP {dd/mm/yyyy}
Once opened, use within 8 weeks

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Betafuse 1 mg/g + 5 mg/g 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 and manufacturer responsible for batch release:
Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Betamethasone (as betamethasone valerate)
Fusidic acid (as fusidic acid hemihydrate)

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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.

4. INDICATION(S)

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 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 12 'Special warning', subsection 'Pregnancy and lactation'.

6. ADVERSE REACTIONS

Prolonged and intensive use of topical corticosteroid preparations or treatment of a large skin surface area (>10%) is known to trigger effects including suppression of adrenal function, thinning of the skin and delayed healing.
Locally applied steroids may cause loss of skin colour.
Discontinue use if hypersensitivity develops to the 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 inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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^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.

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 PERIOD

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.
Once opened, use within 8 weeks.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Pyoderma is often secondary in nature. The underlying cause should be identified and treated.

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 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.
Always wear single-use impermable 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.

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 (symptoms, emergency procedures, antidotes):
For possible signs see the “Adverse reactions” section of this package leaflet.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

For Animal Treatment Only.

DISTRIBUTED BY:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
BT35 6QQ
Co. Down
Northern Ireland

Pack sizes: 15 g or 30 g.
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.

Approved 28 October 2022