PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fuselieve 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. PACKAGE SIZE

15 g
30 g

4. TARGET SPECIES

Dogs

5. INDICATIONS

Cutaneous use.
Read the package leaflet before use.

6. ROUTES OF ADMINISTRATION

Cutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 8 weeks.

9. SPECIAL STORAGE PRECAUTIONS

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

User Warnings
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

(UK)
Norbrook Laboratories Limited.

14. MARKETING AUTHORISATION NUMBERS

Vm 02000/4405

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fuselieve 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. TARGET SPECIES

Dogs

4. ROUTES OF ADMINISTRATION

Cutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 8 weeks

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

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

1. Name of the veterinary medicinal product

Fuselieve 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 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 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 warnings’, 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.
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.

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.

7. Adverse events

Target species: Dogs

Undetermined frequency	Systemic disorder (e.g. suppression of adrenal function[1], thinning of the epidermis[1], delayed healing[1]). Pigmentation disorder (e.g. depigmentation of the skin[2]). Hypersensitivity[3].

[1] May be triggered by prolonged and intensive use of topical corticosteroid preparations or treatment of a large cutaneous surface (>10%).
[2] May be caused by locally applied steroids.
[3] 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 holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: www.hpra.ie.

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^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 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.
Once opened, use within 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 02000/4405

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

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.

16. Contact details

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

(UK (NI/GB)):
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

(EU):
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

Manufacturer Responsible for Batch Release:

(UK (NI/GB)):
Norbrook Laboratories Limited,
Station Works
Camlough Road,
Newry,
County Down,
Northern Ireland
BT35 6JP

(EU):
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

17. OTHER INFORMATION

POM-V

Approved 22 January 2025
Gavin Hall