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

Authorised

- Betamethasone valerate
- Fusidic acid hemihydrate

Product identification

Medicine name:
Betafuse 1 mg/g + 5 mg/g gel for dogs

Active substance:
Betamethasone valerate

Fusidic acid hemihydrate

Target species:
Dog

Route of administration:
Cutaneous use

Product details

Active substance and strength:
Betamethasone valerate
1.21 milligram(s) / 1.00 gram(s)

Fusidic acid hemihydrate

10.17 milligram(s) / 1.00 gram(s)

Pharmaceutical form:
Gel

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QD07CC01

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Portugal

Package description:
White polyethylene coated aluminium tubes of 30 g closed with a polypropylene cap.
White polyethylene coated aluminium tubes of 15 g closed with a polypropylene cap.

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Hybrid application (Article 13(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Norbrook Laboratories (Ireland) Limited

Marketing authorisation date:
5/08/2016

Manufacturing sites for batch release:
Norbrook Laboratories Limited
Norbrook Manufacturing Limited

Responsible authority:

Directorate General For Food And Veterinary

Authorisation number:
1035/01/16DFVPT

Date of authorisation status change:
5/09/2025

Reference member state:
Ireland

Procedure number:
IE/V/0558/001

Concerned member states:
Austria Belgium Denmark Estonia Finland Germany Greece Italy Latvia Lithuania Netherlands Portugal Spain Sweden

United Kingdom (Northern Ireland)

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Summary of Product Characteristics

Combined File of all Documents

English (PDF)
Published on: 26/01/2025
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