

Amflee 134 mg Spot-on Solution for Medium Dogs

Authorised

- Fipronil

Product identification

Medicine name:

Amflee 134 mg Spot-on Solution for Medium Dogs

Active substance:

Fipronil

Target species:

Dog

Route of administration:

Cutaneous use

Product details

Active substance and strength:

Fipronil

134.00 milligram(s) / 1.34 millilitre(s)

Pharmaceutical form:

Spot-on solution

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QP53AX15

Legal status of supply:

Veterinary medicinal product not subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

United Kingdom (Northern Ireland)

Package description:

(ID1) 1.34 millilitre(s): Box (cardboard) with 1 Pipette (polypropylene) with 1.34 millilitre(s)

(ID2) 4.02 millilitre(s): Box (cardboard) with 3 Pipette (polypropylene) each with 1.34 millilitre(s)

(ID3) 8.04 millilitre(s): Box (cardboard) with 6 Pipette (polypropylene) each with 1.34 millilitre(s)

(ID4) 13.4 millilitre(s): Box (cardboard) with 10 Pipette (polypropylene) each with 1.34 millilitre(s)

(ID5) 26.8 millilitre(s): Box (cardboard) with 20 Pipette (polypropylene) each with 1.34 millilitre(s)

(ID6) 40.2 millilitre(s): Box (cardboard) with 30 Pipette (polypropylene) each with 1.34 millilitre(s)

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:

KRKA tovarna zdravil d.d. Novo mesto

Marketing authorisation date:

27/05/2015

Manufacturing sites for batch release:

KRKA tovarna zdravil d.d. Novo mesto
TAD Pharma GmbH

Responsible authority:

The Veterinary Medicines Directorate

Authorisation number:

Vm 01656/4088

Date of authorisation status change:

5/11/2024

Reference member state:

Germany

Procedure number:

DE/V/0191/003

Concerned member states:

France Greece Italy Netherlands Portugal Spain
United Kingdom (Northern Ireland)

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

Documents

Combined File of all Documents

2402109-paren-20180308.rtf