Amflee 50 mg spot-on solution for cats

Authorised

- Fipronil

Product identification

Medicine name:
Amflee 50 mg spot-on solution for cats

Active substance:
Fipronil

Target species:
Cat

Route of administration:
Cutaneous use

Product details

Active substance and strength:
Fipronil
50.00 milligram(s) / 0.50 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:
Germany

Available in:
Germany

Package description:
(ID1) 0.5 millilitre(s): Box (cardboard) with 1 Pipette (polypropylene) with 0.5 millilitre(s), closed with Lid (Not applicable)
(ID2) 1.5 millilitre(s): Box (cardboard) with 3 Pipette (polypropylene) each with 0.5 millilitre(s), closed with Lid (Not applicable)
(ID3) 3 millilitre(s): Box (cardboard) with 6 Pipette (polypropylene) each with 0.5 millilitre(s), closed with Lid (Not applicable)
(ID4) 5 millilitre(s): Box (cardboard) with 10 Pipette (polypropylene) each with 0.5 millilitre(s), closed with Lid (Not applicable)
(ID5) 10 millilitre(s): Box (cardboard) with 20 Pipette (polypropylene) each with 0.5 millilitre(s), closed with Lid (Not applicable)
(ID6) 15 millilitre(s): Box (cardboard) with 30 Pipette (polypropylene) each with 0.5 millilitre(s), closed with Lid (Not applicable)

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:
26/01/2015

Manufacturing sites for batch release:
KRKA tovarna zdravil d.d. Novo mesto
TAD Pharma GmbH

Responsible authority:
Federal Office Of Consumer Protection And Food Safety

Authorisation number:
402107.00.00

Date of authorisation status change:
15/04/2020

Reference member state:
Germany

Procedure number:
DE/V/0191/001

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

English (PDF)

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