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Amflee 2.5 mg/ml cutaneous spray, solution for cats and dogs

Authorised

- Fipronil

Product identification

Medicine name:
Amflee 2.5 mg/ml cutaneous spray, solution for cats and dogs

Active substance:
Fipronil

Target species:
Dog
Cat

Route of administration:
Cutaneous use

Product details

Active substance and strength:
Fipronil
2.50 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Cutaneous spray, 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:
France

Available in:
France

Package description:
(ID1) 100 millilitre(s): unspecified outer container with 1 Bottle (High Density PolyEthylene) with 100 millilitre(s)
(ID2) 250 millilitre(s): unspecified outer container with 1 Bottle (High Density PolyEthylene) with 250 millilitre(s)
(ID3) 500 millilitre(s): unspecified outer container with 1 Bottle (High Density PolyEthylene) with 500 millilitre(s)

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Generic application (Article 13(1) of Directive No 2001/82/EC)

Marketing authorisation holder:
KRKA tovarna zdravil d.d. Novo mesto

Marketing authorisation date:
19/09/2014

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

TAD Pharma GmbH

Responsible authority:
French Agency For Food, Environmental And Occupational Health & Safety

Authorisation number:
FR/V/8535568 8/2014

Date of authorisation status change:
2/09/2019

Reference member state:
Germany

Procedure number:
DE/V/0187/001

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

Summary of Product Characteristics

This document does not exist in this language (English). You can find it in another language below.

Package Leaflet and Labelling

This document does not exist in this language (English). You can find it in another language below.

Combined File of all Documents

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