Fyperix 402 mg spot-on solution for dogs

Authorised

- Fipronil

Product identification

Medicine name:
Fyperix 402 mg spot-on solution for dogs
FYPERIX 402 mg SOLUCION PARA UNCION DORSAL PUNTUAL PARA PERROS

Active substance:
Fipronil

Target species:
Dog

Route of administration:
Cutaneous use

Product details

Active substance and strength:
Fipronil
402.00 milligram(s) / 4.02 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:
Spain

Package description:
(ID6) 120.6 millilitre(s): Box (board) with 30 Beutel (low-density polyethylene; polyethylene terephthalate; aluminium) each with 1 Pipette (polypropylene) with 4.02 millilitre(s)
(ID5) 80.4 millilitre(s): Box (board) with 20 Beutel (low-density polyethylene; polyethylene terephthalate; aluminium) each with 1 Pipette (polypropylene) with 4.02 millilitre(s)
(ID4) 40.2 millilitre(s): Box (board) with 10 Beutel (low-density polyethylene; polyethylene terephthalate; aluminium) each with 1 Pipette (polypropylene) with 4.02 millilitre(s)
(ID3) 24.12 millilitre(s): Box (board) with 6 Beutel (low-density polyethylene; polyethylene terephthalate; aluminium) each with 1 Pipette (polypropylene) with 4.02 millilitre(s)
(ID2) 12.06 millilitre(s): Box (board) with 3 Beutel (low-density polyethylene; polyethylene terephthalate; aluminium) each with 1 Pipette (polypropylene) with 4.02 millilitre(s)
(ID1) 4.02 millilitre(s): Box (board) with Beutel (low-density polyethylene; polyethylene terephthalate; aluminium) with 1 Pipette (polypropylene) with 4.02 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:
30/07/2012

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

Responsible authority:
Spanish Agency Of Medicines And Medical Devices

Authorisation number:
2598 ESP

Date of authorisation status change:
1/01/2023

Reference member state:
Germany

Procedure number:
DE/V/0190/005

Concerned member states:
Finland France Italy Portugal Spain

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

Documents

Summary of Product Characteristics

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