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Atopica 100 mg/ml oral solution for cats and dogs

Authorised

- Ciclosporin

Product identification

Medicine name:
Atopica 100 mg/ml oral solution for cats and dogs

Active substance:
Ciclosporin

Target species:
Dog
Cat

Route of administration:
Oral use

Product details

Active substance and strength:
Ciclosporin
100.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Oral solution

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QL04A

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

Authorisation status:
Valid

Authorised in:
Germany

Available in:
Germany

Package description:
Multi-dose type III amber glass bottle containing 5 ml oral solution closed with a rubber stopper and sealed with a polypropylene child-resistant screw cap. One bottle and a dispenser set (consisting of a PE dip tube and a 1 ml polypropylene syringe) packed in a cardboard box. Pack sizes1 x 5 ml and one dispenser set
Multi-dose type III amber glass bottle containing 17 ml oral solution closed with a rubber stopper and sealed with a polypropylene child-resistant screw cap. One bottle and a dispenser set (consisting of a PE dip tube and a 1 ml polypropylene syringe) packed in a cardboard box. Pack sizes1 x 17 ml and one dispenser set
Multi-dose type III amber glass bottle containing 50 ml oral solution closed with a chlorobutyl rubber stopper and sealed with an aluminium tear-off cap. Each bottle is provided with two dispenser sets (consisting of a PE dip tube and a 1 ml or 4 ml polypropylene syringe) packed in a cardboard box. A polypropylene child-resistant screw cap is provided for closure of the bottle during the in-use period. Pack sizes1 x 50 ml bottle and two dispenser sets

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Full application (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Elanco GmbH

Marketing authorisation date:
19/07/2011

Manufacturing sites for batch release:
Elanco France S.A.S.

Responsible authority:
Federal Office Of Consumer Protection And Food Safety

Authorisation number:
401485.00.00

Date of authorisation status change:
13/08/2016

Reference member state:
Ireland

Procedure number:
IE/V/0881/001

Concerned member states:
Austria Belgium Denmark Finland France Germany Iceland Italy Luxembourg Netherlands Norway Portugal Spain Sweden 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

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