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:
Norway

Available in:
Norway

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:
15/11/2011

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

Responsible authority:
Norwegian Medical Products Agency

Authorisation number:
10-7833

Date of authorisation status change:
15/11/2011

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

Summary of Product Characteristics

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

Package Leaflet

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