

Cyclavance 100 mg/ml oral solution for dogs and cats

Authorised

- Ciclosporin

Product identification

Medicine name:

Cyclavance 100 mg/ml oral solution for dogs and cats

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:

Spain

Available in:

Spain

Package description:

Amber glass (type III) bottles closed with a child resistant HDPE screw cap including aplastic adapter (HDPE).5 ml bottle, with a dispenser set consisting of a 1 ml PE oral syringe graduated in increments of 0.05 ml, packaged in a cardboard box.

Amber glass (type III) bottles closed with a child resistant HDPE screw cap including aplastic adapter (HDPE).15 ml bottle, with a dispenser set consisting of a 1 ml PE oral syringe graduated in increments of 0.05 ml, packaged in a cardboard box.

Amber glass (type III) bottles closed with a child resistant HDPE screw cap including aplastic adapter (HDPE).30 ml bottle, with two dispenser sets consisting of both 1 ml and 2 ml PE oral syringes graduated in increments of respectively 0.05 ml and 0.1 ml, packaged in a cardboard box.

Amber glass (type III) bottles closed with a child resistant HDPE screw cap including aplastic adapter (HDPE).60 ml bottle, with two dispenser sets consisting of both 1 ml and 2 ml PE oral syringes graduated in increments of respectively 0.05 ml and 0.1 ml, packaged in a cardboard box.

Amber glass (type III) bottles closed with a 20 mm bromobutyl stopper and an aluminum cap with flip-off.5 ml bottle with a dispenser set consisting of a polycarbonate dispenser cap with a silicone valve and a 1 ml polypropylene oral syringe graduated in increments of 0.05 ml, packaged in a cardboard box.

Amber glass (type III) bottles closed with a 20 mm bromobutyl stopper and an aluminum cap with flip-off.15 ml bottle with a dispenser set consisting of a polycarbonate dispenser cap with a silicone valve and a 1 ml polypropylene oral syringe graduated in increments of 0.05 mL, packaged in a cardboard box.

Amber glass (type III) bottles closed with a 20 mm bromobutyl stopper and an aluminum cap with flip-off.30 ml bottle, with two dispenser sets consisting of a polycarbonate dispenser capwith a silicone valve and both 1 ml and 3 ml polypropylene oral syringes graduated in increments of respectively 0.05 ml and 0.1 ml, packaged in a cardboard box.

Amber glass (type III) bottles closed with a 20 mm bromobutyl stopper and an aluminum cap with flip-off.50 ml bottle, with two dispenser sets consisting of a polycarbonate dispenser capwith a silicone valve and both 1 ml and 3 ml polypropylene oral syringes graduated in increments of respectively 0.05 ml and 0.1 ml, packaged in a cardboard box.

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:

Virbac

Marketing authorisation date:

26/03/2014

Manufacturing sites for batch release:

Labiana Life Sciences S.A.

Responsible authority:

Spanish Agency Of Medicines And Medical Devices

Authorisation number:

3011 ESP

Date of authorisation status change:

26/01/2015

Reference member state:

Ireland

Procedure number:

IE/V/0523/001

Concerned member states:

Austria Belgium Bulgaria Cyprus Czechia Denmark Estonia Finland France
Germany Greece Hungary Italy Latvia Lithuania Luxembourg Netherlands
Norway Poland Portugal Romania Slovakia Slovenia 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

English (PDF)

Published on: 3/05/2024

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Package Leaflet

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Labelling

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