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MODULIS 100 MG/ML ORAL SOLUTION FOR DOGS

Authorised

- Ciclosporin

Product identification

Medicine name:

MODULIS 100 MG/ML ORAL SOLUTION FOR DOGS

Active substance:

Ciclosporin

Target species:

Dog

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:

QL04AD01

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

France

Available in:

France

Package description:

Box of one 5 mL vial and one 1 mL graduated syringe for oral administration
Box of one 50 mL vial and one 2 mL graduated syringe for oral administration
Box of one 30 mL vial and one 2 mL graduated syringe for oral administration
Box of one 15 mL vial and one 1 mL graduated syringe for oral administration

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:

Ceva Sante Animale

Marketing authorisation date:

14/10/2014

Manufacturing sites for batch release:

Ceva Sante Animale
Laboratoires Biove
Ceva Sante Animale

Responsible authority:

French Agency For Food, Environmental And Occupational Health & Safety

Authorisation number:

FR/V/0321650 5/2014

Date of authorisation status change:

9/09/2019

Reference member state:

France

Procedure number:

FR/V/0339/001

Concerned member states:

Austria Belgium Czechia Denmark Finland Germany Greece Hungary
Ireland Italy Luxembourg Netherlands Norway Poland 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 and Labelling

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

Combined File of all Documents