

# 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

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**Active substance:**

Ciclosporin

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**Target species:**

Dog

Cat

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**Route of administration:**

Oral use

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## Product details

**Active substance and strength:**

Ciclosporin

100.00 milligram(s) / 1.00 millilitre(s)

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**Pharmaceutical form:**

Oral solution

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**Anatomical therapeutic chemical veterinary (ATCvet) codes:**

QL04A

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**Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

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**Authorisation status:**

Valid

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**Authorised in:**

France

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**Available in:**

France

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**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 sizes 1 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 sizes 1 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 sizes 1 x 50 ml bottle and two dispenser sets

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## Additional information

**Entitlement type:**

Marketing Authorisation

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**Legal basis of product authorisation:**

Full application (Article 12(3) of Directive No 2001/82/EC)

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**Marketing authorisation holder:**

Elanco GmbH

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**Marketing authorisation date:**

6/07/2011

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**Manufacturing sites for batch release:**

Elanco France S.A.S.

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**Responsible authority:**

French Agency For Food, Environmental And Occupational Health & Safety

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**Authorisation number:**

FR/V/6460644 4/2011

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**Date of authorisation status change:**

3/06/2016

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**Reference member state:**

Ireland

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**Procedure number:**

IE/V/0881/001

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**Concerned member states:**

Austria Belgium Denmark Finland France Germany Iceland Italy  
Luxembourg Netherlands Norway Portugal Spain Sweden  
United Kingdom (Northern Ireland)

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To consult adverse reactions on veterinary medicinal products please go to  
[www.adrreports.eu/vet](http://www.adrreports.eu/vet)

## Documents

### Summary of Product Characteristics

English (PDF)

Published on: 8/03/2023

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### Package Leaflet and Labelling

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