

Atopica 25 mg soft capsules for dogs

Authorised

- Ciclosporin

Product identification

Medicine name:

Atopica 25 mg soft capsules for dogs

Active substance:

Ciclosporin

Target species:

Dog

Route of administration:

Oral use

Product details

Active substance and strength:

Ciclosporin

25.00 milligram(s) / 1.00 Capsule

Pharmaceutical form:

Capsule, soft

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QL04AD01

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Ireland

Available in:

Ireland

Package description:

Box containing 15 capsules in 3 aluminium/aluminium blister packs

Box containing 30 capsules in 6 aluminium/aluminium blister packs

Box containing 60 capsules in 12 aluminium/aluminium blister packs

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:

17/06/2016

Manufacturing sites for batch release:

Elanco France S.A.S.

Responsible authority:

Health Products Regulatory Authority

Authorisation number:

VPA22020/016/002

Date of authorisation status change:

17/06/2016

Reference member state:

Ireland

Procedure number:

IE/V/0880/002

Concerned member states:

Austria Belgium Denmark Finland France Germany 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