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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:
Germany

Available in:
Germany

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:
8/09/2003

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

Responsible authority:
Federal Office Of Consumer Protection And Food Safety

Authorisation number:
400703.01.00

Date of authorisation status change:
3/11/2008

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

Combined File of all Documents

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Summary of Product Characteristics