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ZELYS 1,25 MG CHEWABLE TABLETS FOR DOGS

Authorised

- Pimobendan

Product identification

Medicine name:
ZELYS 1,25 MG CHEWABLE TABLETS FOR DOGS

Active substance:
Pimobendan

Target species:
Dog

Route of administration:
Oral use

Product details

Active substance and strength:
Pimobendan
1.25 milligram(s) / 1.00 Tablet

Pharmaceutical form:
Chewable tablet

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QC01CE90

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Denmark

Available in:
Denmark

Package description:
Box containing 1 vial of 60 tablets
Box containing 8 blisters of 12 tablets
Box containing 3 blisters of 12 tablets

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Hybrid application (Article 13(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Ceva Sante Animale

Marketing authorisation date:
12/03/2018

Manufacturing sites for batch release:
Ceva Sante Animale

Responsible authority:
Danish Medicines Agency

Authorisation number:
58620

Date of authorisation status change:
12/03/2018

Reference member state:
France

Procedure number:
FR/V/0356/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland Germany Greece Hungary Ireland 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

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Combined File of all Documents

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