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Zelys 10 mg chewable tablets for dogs

Authorised

- Pimobendan

Product identification

Medicine name:
Zelys 10 mg chewable tablets for dogs

Active substance:
Pimobendan

Target species:
Dog

Route of administration:
Oral use

Product details

Active substance and strength:
Pimobendan
10.00 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:
Ireland

Available in:
Ireland

Package description:
Box containing 1 vial of 30 tablets
Box containing 24 blisters of 4 tablets
Box containing 8 blisters of 4 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:
1/06/2018

Manufacturing sites for batch release:
Ceva Sante Animale

Responsible authority:
Health Products Regulatory Authority

Authorisation number:
VPA10815/046/003

Date of authorisation status change:
1/06/2018

Reference member state:
France

Procedure number:
FR/V/0356/003

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

Combined File of all Documents

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