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Fatrobendan 10 mg, chewable tablets for dogs

- Pimobendan

Authorised

Product identification

Medicine name:

Fatrobendan 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:

- PVC/PE/PVdC/PE/PVC blister sealed with thermoheated aluminium foil containing 10 tablets.Pack-sizes:- Cardboard box containing 1 blister of 10 tablets (10 tablets)
- PVC/PE/PVdC/PE/PVC blister sealed with thermoheated aluminium foil containing 10 tablets.Pack-sizes:- Cardboard box containing 5 blisters of 10 tablets (50 tablets)
- PVC/PE/PVdC/PE/PVC blister sealed with thermoheated aluminium foil containing 10 tablets.Pack-sizes:- Cardboard box containing 10 blisters of 10 tablets (100 tablets)

Additional information

Entitlement type:

- Marketing Authorisation

Legal basis of product authorisation:

- Hybrid application – change in strength (Article 19(1)(a) of Regulation (EU) 2019/6)

Marketing authorisation holder:

- Fatro S.p.A.

Marketing authorisation date:

- 19/03/2021

Manufacturing sites for batch release:

- Fatro S.p.A.

Responsible authority:

- Health Products Regulatory Authority

Authorisation number:

- VPA10836/011/003

Date of authorisation status change:

- 19/03/2021

Reference member state:

- Ireland

Procedure number:

- IE/V/0571/003

Concerned member states:

- Cyprus
- Czechia
- Greece
- Lithuania
- Poland
- Portugal
- Slovakia
- Spain
- United Kingdom (Northern Ireland)

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Product information

Summary of Product Characteristics

English (PDF)

Published on: 29/09/2024

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Public assessment report(s)

ie-puar-mr-iev0571003-fatrobendan-10-mg-chewable-tablets-for-dogs-en.pdf

English (PDF)

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