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Fatrobendan 1.25 mg, chewable tablets for dogs

Authorised

- Pimobendan

Product identification

Medicine name:
Fatrobendan 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:
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 10 blisters of 10 tablets (100 tablets)
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)

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:
VPA10836/011/001

Date of authorisation status change:
19/03/2021

Reference member state:
Ireland

Procedure number:
IE/V/0571/001

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

Summary of Product Characteristics
ie-puar-mr-iev0571001-fatrobendan-125-mg-chewable-tablets-for-dogs-en.pdf