Fatrobendan 1.25 mg, chewable tablets for dogs

Authorised

- Pimobendan

Product identification

Medicine name:
Fatrobendan 1.25 mg, chewable tablets for dogs
Fatrobendan 1,25 mg Tabletka do rozgryzania i żucia

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:
Poland

Package description:
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 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 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:
14/10/2024

Manufacturing sites for batch release:
Fatro S.p.A.

Responsible authority:
Office For Registration Of Medicinal Products Medical Devices And Biocidal Products

Authorisation number:
3358

Date of authorisation status change:
14/10/2024

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