

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