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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

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

# Withdrawal period by route of administration: Oral use: Dog

# 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 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: 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 <a href="https://www.adrreports.eu/vet">www.adrreports.eu/vet</a>
Documents
Summary of Product Characteristics

ie-puar-mr-iev0571001-fatrobendan-125-mg-chewable-tablets-for-dogs-en.pdf