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Fatrobendan 5 mg, chewable tablets for dogs

Authorised

Pimobendan

Product identification

Medicine name:

Fatrobendan 5 mg, chewable tablets for dogs Fatrobendan 5 mg comprimidos mastigáveis para cães

Active substance:

Pimobendan

Target species:

Dog

Route of administration:

Oral use

Product details

Active substance and strength:

Pimobendan

5.00 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:

Portugal

Available in:

Portugal

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 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)

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Generic application (Article 13(1) of Directive No 2001/82/EC)

Marketing authorisation holder:

Fatro S.p.A.

Marketing authorisation date: 13/08/2024

Manufacturing sites for batch release:

Fatro S.p.A.

Responsible authority:

Directorate General For Food And Veterinary

Authorisation number:

1658/02/24DFVPT

Date of authorisation status change:

13/08/2024

Reference member state:

Ireland

Procedure number:

IE/V/0571/002

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

Combined File of all Documents

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