Equizol 400 mg gastro-resistant granules for horses

Authorised

- Omeprazole

Product identification

Medicine name:
Equizol 400 mg gastro-resistant granules for horses

Active substance:
Omeprazole

Target species:
Horse

Route of administration:
Oral use

Product details

Active substance and strength:
Omeprazole
80.00 milligram(s) / 1.00 gram(s)

Pharmaceutical form:
Gastro-resistant granules

Withdrawal period by route of administration:

Oral use:

- **Horse**
  - Meat and offal. 2 day
  - Milk. no withdrawal period

Not authorised for use in animals producing milk for human consumption.

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QA02BC01

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

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Authorisation status:

Valid

Authorised in:

France

Available in:

France

Package description:

(ID1) 70 gram(s): Box (cardboard) with 14 Bag (polyethylene; aluminium; paper) each with 5 gram(s)
(ID2) 140 gram(s): Box (cardboard) with 28 Bag (polyethylene; aluminium; paper) each with 5 gram(s)
(ID3) 280 gram(s): Box (cardboard) with 56 Bag (polyethylene; aluminium; paper) each with 5 gram(s)
(ID4) 420 gram(s): Box (cardboard) with 84 Bag (polyethylene; aluminium; paper) each with 5 gram(s)
(ID5) 500 gram(s): Box (cardboard) with 100 Bag (polyethylene; aluminium; paper) each with 5 gram(s)
(ID6) 560 gram(s): Box (cardboard) with 112 Bag (polyethylene; aluminium; paper) each with 5 gram(s)

(ID7) 1000 gram(s): Box (cardboard) with 200 Bag (polyethylene; aluminium; paper) each with 5 gram(s)

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Hybrid application (Article 13(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
CP-Pharma Handelsgesellschaft mbH

Marketing authorisation date:
14/06/2018

Manufacturing sites for batch release:
CP-Pharma Handelsgesellschaft mbH

Responsible authority:
French Agency For Food, Environmental And Occupational Health & Safety

Authorisation number:
FR/V/2083897 9/2018

Date of authorisation status change:
5/01/2023

Reference member state:
Germany

Procedure number:
DE/V/0318/001

Concerned member states:
Austria Belgium Czechia Denmark Finland France Hungary Ireland Italy Netherlands Norway Poland Portugal Slovakia Spain Sweden

United Kingdom (Northern Ireland)

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Summary of Product Characteristics

This document does not exist in this language (English). You can find it in another language below.

Package Leaflet and Labelling

This document does not exist in this language (English). You can find it in another language below.

Combined File of all Documents

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