Peptizole 370 mg/g Oral Paste for Horses

Authorised

- Omeprazole

Product identification

Medicine name:
Peptizole 370 mg/g Oral Paste for Horses
Ulcergold 370 mg/g Pasta oral para equinos

Active substance:
Omeprazole

Target species:
Horse

Route of administration:
Oral use

Product details

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

Pharmaceutical form:
Oral paste

Withdrawal period by route of administration:

Oral use:

- **Horse**

  - Meat and offal. 1 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QA02BC01

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Portugal

Package description:
Immediate package Immediate packaging: 7 ml oral syringe containing 7.57 g of paste composed of polyethylene barrel, plunger and end cap, with polypropylene dosing rings. Outer package and sales presentations - Bucket of 72 oral syringes Immediate package Immediate packaging: 7 ml oral syringe containing 7.57 g of paste composed of polyethylene barrel, plunger and end cap, with polypropylene dosing rings. Outer package and sales presentations - Carton box of 7 oral syringes Immediate package Immediate packaging: 7 ml oral syringe containing 7.57 g of paste composed of polyethylene barrel, plunger and end cap, with polypropylene dosing rings. Outer package and sales presentations - Carton box of 1 oral syringe

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:
Norbrook Laboratories (Ireland) Limited

Marketing authorisation date:
18/10/2013

Manufacturing sites for batch release:
Norbrook Laboratories Limited
Norbrook Manufacturing Limited

Responsible authority:
Directorate General For Food And Veterinary

Authorisation number:
727/01/13DFVPT

Date of authorisation status change:
11/04/2022

Reference member state:
Ireland

Procedure number:
IE/V/0307/001

Concerned member states:
Austria Belgium Czechia Estonia Finland France Hungary Italy Latvia Lithuania Luxembourg Malta Netherlands 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

Combined File of all Documents

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