Peptizole 370 mg/g Oral Paste for Horses

Authorised

- Omeprazole

Product identification

Medicine name:
Peptizole 370 mg/g Oral Paste for Horses

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:

Estonia

Package description:

Immediate packageImmediate packaging: 7 ml oral syringe containing 7.57 g of paste composed ofpolyethylene barrel, plunger and end cap, with polypropylene dosing rings.Outer package and sales presentations- Carton box of 1 oral syringe Immediate packageImmediate packaging: 7 ml oral syringe containing 7.57 g of paste composed ofpolyethylene barrel, plunger and end cap, with polypropylene dosing rings.Outer package and sales presentations- Carton box of 7 oral syringes Immediate packageImmediate packaging: 7 ml oral syringe containing 7.57 g of paste composed ofpolyethylene 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 14 oral syringes

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:
26/09/2013

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

Responsible authority:
State Agency Of Medicines

Authorisation number:
1787

Date of authorisation status change:
26/09/2013

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

English (PDF)
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Combined File of all Documents