

GastroGard 370 mg/g oral paste

Authorised

- Omeprazole

Product identification

Medicine name:

GastroGard 370 mg/g oral paste

Gastrogard 370 mg/g pasta voor oraal gebruik voor paarden

Active substance:

Omeprazole

Target species:

Horse

Route of administration:

Oral use

Product details

Active substance and strength:

Omeprazole

2.28 gram(s) / 1.00 Syringe

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:

Netherlands

Package description:

Immediate packaging: 10 ml syringe containing 6.16 g of paste composed of white polypropylene syringes barrel with a white LDPE cap, a rubber rod tip and a polypropylene plunger rod, with dose divisions calibrated by body weight. Outer packaging and sales presentations-Bulk pack of 72 syringes

Immediate packaging: 10 ml syringe containing 6.16 g of paste composed of white polypropylene syringes barrel with a white LDPE cap, a rubber rod tip and a polypropylene plunger rod, with dose divisions calibrated by body weight. Outer packaging and sales presentations-Carton box of 14 syringes

Immediate packaging: 10 ml syringe containing 6.16 g of paste composed of white polypropylene syringes barrel with a white LDPE cap, a rubber rod tip and a polypropylene plunger rod, with dose divisions calibrated by body weight. Outer packaging and sales presentations-Carton box of 7 syringes

Immediate packaging: 10 ml syringe containing 6.16 g of paste composed of white polypropylene syringes barrel with a white LDPE cap, a rubber rod tip and a polypropylene plunger rod, with dose divisions calibrated by body weight. Outer packaging and sales presentations-Carton box of 1 syringe

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Full application (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:

Boehringer Ingelheim Animal Health Netherlands B.V.

Marketing authorisation date:

3/03/2004

Manufacturing sites for batch release:

Boehringer Ingelheim Animal Health France

Responsible authority:

Medicines Evaluation Board

Authorisation number:

REG NL 10155

Date of authorisation status change:

27/01/2022

Reference member state:

Ireland

Procedure number:

IE/V/0489/001

Concerned member states:

Austria Belgium Denmark Finland France Germany Greece Italy
Luxembourg Netherlands Norway Portugal 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

Combined File of all Documents

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