SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Peptizole 370 mg/g Oral Paste for Horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:
Omeprazole: 370 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Yellow Iron Oxide (E 172)	2 mg
Ethanolamine	
Cinnamon Leaf Oil	
Liquid Paraffin	

A yellow to tan oily paste.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

For the treatment and prevention of gastric ulcers in horses.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Not recommended for animals under 4 weeks of age or weighing less than 70 kg bodyweight.
The veterinarian should consider the need for performing relevant diagnostic tests before selection of the treatment dose rate.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Stress (including high performance training and competition), feeding, management and husbandry practices may be associated with the development of gastric ulceration in horses. Individuals responsible for the wellbeing of horses should consider reducing the ulcerogenic challenge by modifying husbandry practices to achieve one or more of the following: reduced stress, reduced fasting, increased intake of roughage and access to grazing.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

As this product may cause irritant and hypersensitivity reactions, avoid direct contact with skin and eyes. Use impervious gloves and do not eat or drink when handling and administering the veterinary medicinal product. Wash hands or any exposed skin after use. In case of contact with eyes, wash immediately with clean running water, seek medical advice and show the package leaflet or label to the physician. Persons developing a reaction after contact with the product should seek medical advice and avoid handling the product in future.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

In cases of hypersensitivity reactions, treatment should be discontinued immediately.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic effect.

The safety of the veterinary medicinal product has not been assessed during pregnancy and lactation. The use of the veterinary medicinal product is not recommended in pregnant and lactating mares.

3.8 Interaction with other medicinal products and other forms of interaction

Omeprazole may delay the elimination of warfarin. No other interaction with medicines routinely used in the treatment of horses is expected, although interaction with drugs metabolised by liver enzymes cannot be excluded.

3.9 Administration routes and dosage

For oral administration.

Omeprazole is effective in horses of various breeds and under different management conditions; foals as young as four weeks of age and weighing over 70 kg; and breeding stallions.

Treatment of gastric ulcers: one administration per day during 28 consecutive days at the dose rate of 4 mg omeprazole per kg body weight (1 division of the oral syringe/50 kg BW) followed immediately by a dosage regimen of one administration per day during 28 consecutive days at the dose rate of 1 mg omeprazole per kg body weight, to reduce the recurrence of gastric ulcers during treatment.
Should recurrence occur, re-treatment at a dose rate of 4 mg omeprazole per kg body weight (1 division of the oral syringe/50 kg BW) is recommended.
It is recommended to associate the treatment with changes of husbandry and training practices. Please see also the text under section 3.5

Prevention of gastric ulcers: one administration per day at the dose rate of 1 mg omeprazole per kg body weight.

To deliver omeprazole at the dose of 4 mg omeprazole /kg, set the oral syringe plunger to the appropriate dose division for the horse’s weight. Each division on the oral syringe plunger delivers sufficient omeprazole to treat 50 kg body weight. The contents of one oral syringe will treat a 700 kg horse at the rate of 4 mg omeprazole per kg body weight.

To deliver omeprazole at the dose of 1 mg omeprazoleper kg, set the oral syringe plunger to the dose division equivalent to one quarter of the horse’s body weight. For example, to treat a horse weighing 400 kg, set the plunger to 100 kg. At this dose, each division on the oral syringe plunger will deliver sufficient omeprazole to treat 200 kg body weight.

Replace cap after use.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No undesirable effects related to treatment were observed following daily use for 91 days at omeprazole dosages up to 20 mg/kg in adult horses and in foals older than 2 months.

No undesirable effects related to treatment (in particular no adverse effect on the semen quality or reproductive behaviour) were observed following daily use for 71 days at an omeprazole dosage of 12 mg/kg in breeding stallions.

No undesirable effects related to treatment were observed following daily use for 21 days at an omeprazole dosage of 40 mg/kg in adult horses.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Meat and offal: 1 day
Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QA 02 BC 01

4.2 Pharmacodynamics

In studies lasting up to 28 days, treatment with omeprazole at the dose rate of 1 mg omeprazole per kg body weight per day has been shown to help prevent the occurrence of gastric ulcers in horses exposed to ulcerogenic conditions.

Omeprazole is a proton pump inhibitor belonging to the substituted benzimidazole class of compounds. It is an antacid, for treatment of peptic ulcers.

Omeprazole suppresses gastric acid secretion by specific inhibition of the H+/K+-ATPase enzyme system at the secretory surface of the parietal cell. The H+/K+- ATPase enzyme system is the acid (proton) pump within the gastric mucosa. Because H+/K+-ATPase is the final step involved in control of acid secretion, omeprazole blocks secretion irrespective of the stimulus. Omeprazole irreversibly binds to the gastric parietal cell H+/K+- ATPase enzyme that pumps hydrogen ions into the lumen of the stomach in exchange for potassium ions.
At 8, 16 and 24 hours after dosing horses with omeprazole at 4 mg/kg per day orally, pentagastrin-stimulated gastric acid secretion was inhibited by 99%, 95% and 90% and basal secretion was inhibited by 99%, 90% and 83%.

The full effect on the inhibition of acid secretion is reached by five days after the first administration.

4.3 Pharmacokinetics

The median bioavailability of omeprazole after oral administration as a paste is 10.5% (range 4.1 to 12.7%). The absorption is rapid with time to maximum plasma concentrations (Tmax) of approximately 1.25 hours after dosing. Cmax values for individual animals ranged between 121 ng/ml and 1470 ng/ml after one administration of the veterinary medicinal product at 4 mg/kg. There is a significant first-pass effect following oral administration. Omeprazole is rapidly metabolised principally into glucuronides of demethylated and hydroxylated omeprazole sulphide (urinary metabolites) and methyl sulphide omeprazole (biliary metabolite) as well as into reduced omeprazole (both).
After oral administration at 4 mg/kg, omeprazole is detectable in plasma for 9 hours after treatment and in urine as hydroxy omeprazole and O-desmethyl omeprazole at 24 hours but not at 48 hours. Omeprazole is eliminated quickly, mainly by urinary route (43 to 61% of the dose), and to a smaller extent by faecal route, with a terminal half-life ranging from approximately 0.5 to 8 hours.

After repeated oral administration, there is no evidence of accumulation.

5. PHARMACEUTICAL PARTICULARS

5.1 Major Incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 30°C.
Replace cap after use.

5.4 Nature and composition of immediate packaging

7 ml oral syringe containing 7.57 g of paste composed of polyethylene barrel, plunger and end cap, with polypropylene dosing rings.
Cartons of 1, 7, 14 or 21 oral syringes or buckets of 72 oral syringes.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products.

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

7. MARKETING AUTHORISATION NUMBER

Vm 02000/4389

8. DATE OF FIRST AUTHORISATION

04 March 2014

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

April 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

POM - V

Gavin Hall
Approved: 30 April 2026