SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GastroGard 370 mg/g oral paste for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:

Omeprazole:
.....3
70 mg

Excipients:

Yellow Iron Oxide (E 172)….....2 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Smooth homogeneous yellow to yellow-tan paste.

4. CLINICAL PARTICULARS

4.1 Target species

Horses.

4.2 Indications for use, specifying the target species

For treatment and prevention of gastric ulcers in horses.

4.3 Contraindications

Do not use in mares producing milk for human consumption.
See section 4.5.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
Not recommended for animals under 4 weeks of age or weighing less than 70 kg bodyweight.
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 well-being 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 hypersensitivity, avoid direct contact with skin and eyes. Personal protective clothing consisting of impervious gloves should be worn when handling the
product. Do not eat or drink when handling and administering the product. Wash hands or any
exposed skin after use. In case of contact with eyes, wash immediately with clean running water and seek medical advice and show the label/leaflet to the physician.
Persons developing a reaction after contact with the product should avoid handling the product in future.

Special precautions for the protection of the environment
Not applicable.

Other precautions
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Horses:
None known.

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 holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic effect.
In the absence of data during pregnancy and lactation, the use of the veterinary medicinal product in pregnant and lactating mares is not recommended.

4.8 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.

4.9 Amount(s) to be administered and administration route

For oral administration.
Veterinary medicinal product 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 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 is recommended.
It is recommended to associate the treatment with changes of husbandry and training practices. Please see also the text under section 4.5.

Prevention of gastric ulcers: one administration per day at the dose rate of 1 mg omeprazole per kg body weight.
To deliver the veterinary medicinal product at the dose of 4 mg omeprazole/kg, set the syringe plunger to the appropriate dose division for the horse's weight. Each full dose division on the syringe plunger delivers sufficient omeprazole to treat 100 kg body weight. The contents of one syringe will treat a 575 kg horse at the rate of 4 mg omeprazole per kg body weight.
To deliver the veterinary medicinal product at the dose of 1 mg omeprazole/kg, set the syringe plunger to the dose division equivalent to one quarter of the horse's body weight. At this dose, each full dose division on the syringe plunger will deliver sufficient omeprazole to treat 400 kg body weight. For example, to treat a horse weighing 400 kg, set the plunger to 100 kg.
Replace cap after use.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Meat and offal: 1 day.

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

5. PHARMACOLOGICAL PROPERTIES

ATCvet code: QA02BC01.

5.1 Pharmacodynamic properties

In studies lasting up to 28 days, treatment with the veterinary medicinal product 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/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.

5.2 Pharmacokinetic particulars

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 one hour after dosing. Mean peak concentration (Cmax) ranges from 385 ng/ml to 693 ng/ml after dosing with 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 hydroxyomeprazole and O-desmethylomeprazole 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Yellow Iron Oxide (E 172)
Monoethanolamine
Potassium sorbate
Cassia Oil
Sodium Stearate
Calcium Stearate
Hydrogenated Castor Oil
Propylene Glycol Octanoate Decanoate
Sesame Oil

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Immediate packaging: 10 ml syringe, containing 6.16 g of paste, is composed of white polypropylene syringe 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, 7 or 14 syringes

- Bulk pack of 72 syringes.

Not all pack sizes may be marketed.

6.6 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.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 08327/5027

9. DATE OF FIRST AUTHORISATION

09 January 2003

10. DATE OF REVISION OF THE TEXT

March 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall

Approved 25 October 2024