Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Gastrobim 370 mg/g oral paste for horses

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:

Omeprazole	370 mg

Excipients:

Yellow iron oxide (E 172)	4 mg
Potassium sorbate (E 202)	3 mg
Butylhydroxytolune (E 321)	0.5 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral paste.
Smooth homogeneous tan coloured 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.

4.3 Contraindications

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
The product should not be used in animals under 4 weeks of age or weighing less than 70 kg body weight.
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.
The veterinarian should consider the need for performing relevant diagnostic tests before use of the product.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
As this product may cause irritation and hypersensitivity reactions, avoid direct contact with skin and eyes. Use impervious gloves and do not eat or drink when handling and administering the product. Wash hands or any exposed skin after use. Oral syringe should be returned to the original carton and suitably stored to prevent access by children.

In case of contact with eyes, wash immediately with clean running water and seek medical advice and show the package leaflet or the label to the physician if symptoms persist. Persons developing a reaction after contact with the product should avoid handling the product in future.

4.6 Adverse reactions (frequency and seriousness)

There are no known treatment-related clinical adverse effects. However, hypersensitivity reactions cannot be excluded. In cases of hypersensitivity reactions, treatment should be discontinued immediately.

4.7 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 established during pregnancy and lactation in the target species; the use of the product in pregnant and lactating mares is not recommended.

4.8 Interaction with other medicinal products and other forms of interactions

Omeprazole may delay the elimination of warfarin.
Omeprazole may potentially alter benzodiazepine metabolism and prolong CNS effects.
Sucralfate may decrease bioavailability of orally administered omeprazole.
Omeprazole may decrease oral absorption of cyanocobalamin.
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 Amounts to be administered and administration route

Oral use.

Treatment of gastric ulcers: 4 mg omeprazole per kg body weight, corresponding to 1 division of the syringe per 100 kg bodyweight, once daily for 28 consecutive days.
To reduce the recurrence of gastric ulcers during treatment, it should be followed immediately by a dosage regimen of 1 mg omeprazole per kg body weight, corresponding to 1 division of the syringe per 400 kg bodyweight, once daily for 28 consecutive days.
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: 1 mg omeprazole per kg body weight, corresponding to 1 division of the syringe per 400 kg bodyweight, once daily.
To deliver the 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 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 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.

4.11 Withdrawal period(s)

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD), proton pump inhibitors.
ATC vet code: QA02BC01.

5.1 Pharmacodynamic properties

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 (T_{max}) 0.5 to 2 hours after dosing. Mean peak concentration (C_{max}) ranges from 183 ng/ml to 668 ng/ml after dosing with 4 mg/kg bw. 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 bw, omeprazole is detectable in plasma for 6 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 2.05 hours.
After repeated oral administration, there is no evidence of accumulation.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxytoluene (E 321)
Calcium stearate
Castor oil hydrogenated
Triglycerides medium-chain
Monoethanolamine
Potassium sorbate (E 202)
Sesame oil, refined
Sodium stearate
Yellow iron oxide (E 172)
Apple flavour

6.2 Major incompatibilities

Not applicable.

6.3 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.

6.4 Special precautions for storage

Store below 30 °C. Replace cap after use.

6.5 Nature and composition of immediate packaging

White high density polyethylene syringe barrel and plunger with low density polyethylene cap. Syringe contains 6.16 g paste.

Package sizes:
Carton box of 1, 7 or 14 pre-filled oral syringes.
Multipack of 72 pre-filled oral syringes.

Not all pack sizes may be marketed.

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

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

Bimeda Animal Health Limited
2, 3 & 4 Airton Close
Airton Road
Tallaght
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22033/072/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 09 October 2020

10 DATE OF REVISION OF THE TEXT