GASTROBIM

370 mg/g Oral Paste for Horses

Omeprazole

DATA SHEET

INDICATIONS

A tan-coloured paste containing 370 mg/g omeprazole.

Each syringe contains 6.16g of paste.

For treatment and prevention of gastric ulcers in horses.

BENEFITS

- Licensed for the treatment and prevention of gastric ulcers in horses
- Contains apple flavour
- 14 syringe carton made from widely recycled materials
- 2 year shelf life

LIST No	UNIT PACKAGE	CASE SIZE
1BIM290	14 syringe pack	1

See reverse for Administration & Dosage

Gastrobim

370 mg/g Oral Paste for Horses

Omeprazole

DOSE AND ADMINISTRATION ROUTE

For oral administration.

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

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 Gastrobim 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 Gastrobim 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.

CONTRAINDICATIONS AND SPECIAL PRECAUTIONS

Do not use in mares producing milk for human consumption. Do not use in cases of hypersensitivity to the active substance or to any of the excipients. Not recommended for 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.Do not use in known cases of hypersensitivity to the active substance or any of the excipients.

Special precautions to be taken by the person administering the product to animals
As this product may cause hypersensitivity, 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. In case of contact with eyes, wash immediately with clean running water and seek medical advice. Persons developing a reaction after contact with the product should avoid handling the product in future.

ADVERSE REACTIONS

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.

OVERDOSE

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

USE DURING 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 Gastrobim in pregnant and lactating mares is not recommended.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

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.

WITHDRAWAL PERIOD

Meat and offal: 1 day.
Not permitted for use in mares producing milk for human consumption

PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Drugs for peptic ulcer, proton pump inhibitors.

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.

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 0.5-2 hours after dosing. Mean peak concentration (Cmax) ranges from 183ng/ml to 668 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 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.

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.

STORAGE

Store below 30 °C. Replace cap after use.

LEGAL CATEGORY

POM

MARKETING AUTHORISATION NUMBER

VPA 22033/072/001

MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
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Use Medicines Responsibly

A full product SPC is available on request from Bimeda or alternatively can be found on the HPRA website.

TAKE TIME OBSERVE LABEL DIRECTIONS

www.bimeda.ie