

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gastrobim 370 mg/g oral paste for horses (AT, BE, FR, IE, LT, LV, NL)

Bimeprazol 370 mg/g oral paste for horses (DE, ES, IT, PL, PT)

Gastrobim 370 mg/g oral paste for horses (EE)

Gastrobim vet 370 mg/g oral paste for horses (SE)

Gastrobim vet 370 mg/g oral paste for horses (DK)

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)	4 mg
Potassium sorbate (E 202)	3 mg
Butylhydroxytoluene (E 321)	0.5 mg
Calcium stearate	
Castor oil hydrogenated	
Triglycerides medium-chain	
Monoethanolamine	
Sesame oil, refined	
Sodium stearate	
Apple flavour	

Smooth homogeneous tan coloured paste.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

For treatment and prevention of gastric ulcers.

3.3 Contraindications

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The veterinary medicinal 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 veterinary medicinal 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.

People with known hypersensitivity to Omeprazole should avoid contact with the veterinary medicinal product.

Personal protective equipment consisting of protective clothing including impervious gloves should be worn when handling the veterinary medicinal 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 accidental contact with eyes, seek medical advice immediately and show the package leaflet or the label to the physician. Persons developing a reaction after contact with the product should avoid the veterinary medicinal product in future.

Special precautions for the protection of the environment:

See the 5.5 section of the summary of product characteristics.

3.6 Adverse events

Undetermined frequency (cannot be estimated from the available data)	Hypersensitivity reaction ¹
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¹In case 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 holder or the national competent authority via national reporting system.

See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

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

The use is not recommended during pregnancy and lactation.

3.8 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.

3.9 Administration routes and dosage

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 3.5.

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 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.

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.

Milk: Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QA02BC01

4.2 Pharmacodynamics

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.

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 (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.

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

Store below 30 °C.

Replace cap after use.

5.4 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.

Pack 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.

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

Medicines should not be disposed of via wastewater or household waste.

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 system applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: DD/MM/YYYY

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

MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

**CARTON BOX 1 SYRINGE, 7 SYRINGES, 14 SYRINGES.
MULTIPACK OF 72 SYRINGES**

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Gastrobim 370 mg/g oral paste (EE)
Gastrobim vet 370 mg/g oral paste (SE)
Gastrobim vet 370 mg/g oral paste (DK)

2. STATEMENT OF ACTIVE SUBSTANCES

Omeprazole 370 mg/g

3. PACKAGE SIZE

1 x 6.16 g syringe
7 x 6.16 g syringes
14 x 6.16 g syringes
72 x 6.16 g syringes

4. TARGET SPECIES

Horses.

5. INDICATIONS**6. ROUTES OF ADMINISTRATION**

Oral use.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Store below 30 °C.
Replace cap after use.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”
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Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”
--

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”
--

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

14. MARKETING AUTHORISATION NUMBERS
--

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS SYRINGES
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1. NAME OF THE VETERINARY MEDICINAL PRODUCT
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Gastrobim vet 370 mg/g oral paste for horses (SE)
Gastrobim vet 370 mg/g oral paste for horses (DK)



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE
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Omeprazole 370 mg/g

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 28 days.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Gastrobim 370 mg/g oral paste for horses (AT, BE, EE, FR, IE, LT, LV, NL)

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Gastrobim 370 mg/g oral paste for horses (EE)

Gastrobim vet 370 mg/g oral paste for horses (SE)

Gastrobim vet 370 mg/g oral paste for horses (DK)

2. Composition

Each gram contains:

Active substance:

Omeprazole 370 mg

Excipients:

Yellow iron oxide (E 172) 4 mg

Potassium sorbate (E 202) 3 mg

Butylhydroxytoluene (E 321) 0.5 mg

Smooth homogeneous tan coloured paste.

3. Target species

Horses.

4. Indication for use

Treatment and prevention of gastric ulcers.

5. Contraindications

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

6. Special warnings

Special warnings:

None.

Special precautions for safe use in the target species:

The veterinary medicinal 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 veterinary medicinal 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.

People with known hypersensitivity to Omeprazole should avoid contact with the veterinary medicinal product.

Personal protective equipment consisting of protective clothing including impervious gloves should be worn when handling the veterinary medicinal 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 accidental contact with eyes, seek medical advice immediately and show the package leaflet or the label to the physician. Persons developing a reaction after contact with the product should avoid the veterinary medicinal product in future.

Special precautions for the protection of the environment:

See the Special precautions for disposal section of the package leaflet.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

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

The use is not recommended during pregnancy and lactation.

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.

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.

Major incompatibilities:

Not applicable.

7. Adverse events

Undetermined frequency (cannot be estimated from the available data)	Hypersensitivity reaction ¹
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¹In case of hypersensitivity reactions, treatment should be discontinued immediately.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report

any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

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.

It is recommended to associate the treatment with changes of husbandry and training practices. Please see also section 12 “Special precautions for use in animals”.

Should recurrence occur, re-treatment at a dose rate of 4 mg omeprazole per kg body weight is recommended.

Prevention of gastric ulcers: 1 mg omeprazole per kg body weight, corresponding to 1 division of the syringe per 400 kg bodyweight, once daily.

9. Advice on correct administration

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 veterinary medicinal product at the dose of 1 mg omeprazole/kg, set the syringe plunger to the dose division equivalent to one quarter 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.

10. Withdrawal periods

Meat and offal: 1 day.

Milk: Not authorised for use in animals producing milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

Store below 30 °C.

Replace cap after use.

Shelf life after first opening the container: 28 days.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

MA numbers:

Pack 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.

15. Date on which the package leaflet was last revised

MM/YYYY

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<https://medicines.health.europa.eu/veterinary>).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions: