1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Omeproshield 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	
Potassium sorbate	
Cassia Oil	
Sodium Stearate	
Calcium Stearate	
Hydrogenated Castor Oil	
Propylene Glycol dicaprylocaprate	
Sesame Oil, refined	

Smooth homogeneous yellow to yellow-tan paste.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

For the prevention of gastric ulcers.

3.3 Contraindications

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.
See section 3.5.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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. 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.

3.6 Adverse events

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.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

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

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

Oral use.
The 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.

One administration per day for up to 28 consecutive days at a dose rate of 1 mg omeprazole per kg body weight.

It is recommended to associate use of the product with changes of husbandry and training practices. Please see also the text under section 3.5.

Each syringe contains 4 individual daily doses for horses weighing 300 - 544 kg.
Please refer to the following dosage chart for help in determining the correct dosage for your horse.

Omeproshield 370 mg/g oral paste for horses dosage chart	
Horse weight	Dosage
< 300 kg	Consult a veterinarian
300 kg - 544 kg	1 dose per day
> 544 kg	2 doses to be administered consecutively as a single daily dose

Instructions for use:
1. To set the syringe plunger, while holding plunger, turn the knurled ring on the plunger one quarter turn to the left and slide the knurled ring along the plunger shaft so that the side nearest the barrel is at the appropriate daily dose marking, aligning the arrow on the plunger with the notch on the ring.
2. Lock the ring in place by making one quarter turn to the right. Ensure it is locked (it should no longer slide). Make sure the horse's mouth contains no feed before administration.
3. Remove syringe tip cover.
4. Insert syringe into the corner of the horse's mouth.
5. Depress the plunger until it stops at the dose ring. The entire dose should be deposited on the back of the tongue or deep in the cheek pouch.
6. Horses should be observed briefly to assure no part of the dose is lost or rejected.

Replace cap after use.

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

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.

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

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Not applicable.

3.12 Withdrawal periods

Meat and offal: 1 day.

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QA02BC01.

4.2 Pharmacodynamics

In studies lasting up to 28 days, treatment with the 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.

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 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 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.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Immediate packaging: 10 ml syringe containing 6.16 g of paste composed of white polypropylene syringe barrel with a white LDPE cap, a rubber rod tip and a polypropylene plunger rod, with dose divisions.

Outer package and sales presentations:
- Carton box of 7 syringes.
- Carton box of 1 syringe.

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 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 systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH,

7. MARKETING AUTHORISATION NUMBER(S)

VPA10454/071/001

8. DATE OF FIRST AUTHORISATION

13/03/2015

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

16/11/2026

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).