1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gastazole 370 mg/g oral paste for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g paste 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**
Ferric Oxide Yellow (E172)	2 mg
Potassium Sorbate (E202)	-
Ethanolamine	-
Cassia Oil	-
Hydrogenated Castor Oil	-
Calcium Stearate	-
Sodium Stearate	-
Sesame Oil, Refined	-
Propylene Glycol Dicaprylocaprate	-

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 treatment of gastric ulcers and the prevention of recurrence 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:

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 veterinary medicinal product should not be used in animals under 4 weeks of age or weighing less than 70 kg bodyweight. 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 veterinary medicinal product may cause irritation and hypersensitivity reactions, avoid direct contact with skin and eyes. People with known hypersensitivity to omeprazole or any of the excipients should avoid contact with the veterinary medicinal product. Personal protective equipment consisting of impervious gloves should be worn when handling the veterinary medicinal product. Do not eat or drink when handling and administering the veterinary medicinal product. Wash hands or any exposed skin after use. The dosing syringe should be returned to the original packaging 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 veterinary medicinal product should avoid handling in future.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses:

None known.
However, hypersensitivity reactions cannot be excluded. In cases 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 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:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation in the target species; the use of the veterinary medicinal product in pregnant or lactating mares is not recommended.

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

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: 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 3.5.

Prevention of recurrence of gastric ulcers: one administration per day at the dose rate of 1 mg omeprazole per kg body weight.

To deliver the veterinary product at the dose of 4 mg omeprazole/kg, set the syringe plunger to the appropriate dose division for the horse's weight. Each 100 kg dose division on the syringe plunger delivers sufficient omeprazole to treat 100 kg body weight. The contents of one syringe will treat a 700 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 100kg 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.

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}) of approximately one hour after dosing. Peak concentration (C_{max}) ranged from 159.96-2,651.48 ng/ml with mean 637.28 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 sulfide (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 8 hours after treatment. 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 0.6 to 14.7 hours.

After repeated oral administration, there is no evidence of accumulation.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 27 months.

Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 30 ºC. Replace cap after use.

5.4 Nature and composition of immediate packaging

Immediate package

Immediate packaging: Opaque white pre-filled oral syringe containing 7.57 g of paste composed of

Barrel: HDPE & LLDPE
Barrel Cap: LDPE
Plunger: Polypropylene
Ring: Polypropylene
Plastic Seal: LDPE

Package sizes

- Carton box of 1 syringe
- Carton box of 7 syringes

- Carton box of 10 syringes
- Carton box of 14 syringes
- Carton box of 20 syringes
- Carton box of 56 syringes
- Carton box of 72 syringes (bulk pack)

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 systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10987/124/001

8. DATE OF FIRST AUTHORISATION

15/05/2020

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

03/04/2025

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).