SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gastazole 370 mg/g Oral Paste for Horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Omeprazole 370 mg

Excipients:
Ferric Oxide Yellow (E172) 2 mg

3. PHARMACEUTICAL FORM

Oral 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 cases of hypersensitivity to the active substance or to any of the excipient(s).

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals
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 product should not be used in animals under 4 weeks of age or weighing less than 75 kg bodyweight.

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 and/or sesame 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 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 product should avoid handling the product in future.

Special precautions for the protection of the environment
Not applicable

Other precautions
Not applicable

4.6 Adverse reactions (frequency and seriousness)

None known.

Do not use in cases of hypersensitivity to the active substance or to any of the excipient(s).

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 also the last section of the package leaflet for contact details.

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 is not recommended during pregnancy and lactation.

4.8 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. Clarithromycin may increase levels of omeprazole. Omeprazole may reduce cyclosporine metabolism. Omeprazole may decrease absorption of drugs requiring decreased gastric pH for optimal absorption (ketoconazole, itraconazole, iron, ampicillin esters).

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 Amount(s) to be administered and administration route

Effective in horses of various breeds and under different management conditions; foals as young as four weeks of age and weighing over 75 kg; and breeding stallions.

For 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 4.5.

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

To ensure a correct dosage, body weight should be determined as accurately as possible.

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 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 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.

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 mares producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Drugs for peptic ulcer, 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 (Tmax) of approximately one hour after dosing.

Peak concentration (Cmax) ranged from 64.64- 237.21 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 0.7 to 4.1 hours.
After repeated oral administration, there is no evidence of accumulation.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ferric Oxide Yellow (E172)
Ethanolamine
Potassium sorbate
Cassia Oil
Sodium Stearate
Calcium Stearate
Castor Oil Hydrogenated
Propylene Glycol Dicaprylocaprate
Sesame Oil Refined

6.2 Major Incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 27 months.
Shelf life after opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25ºC. Replace cap after use

6.5 Nature and composition of immediate packaging

<u>Immediate package</u>
Immediate packaging: Opaque white pre-filled oral syringe containing 7.57g of paste composed of

Barrel:	Polyethylene LLDPE & HDPE
Barrel Cap:	LDPE or LLDPE & HDPE
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

6.6 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.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co Galway
H62 FH90
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 08749/3163

9. DATE OF FIRST AUTHORISATION

10 July 2024

10. DATE OF REVISION OF THE TEXT

April 2026

PROHIBITION OF SALE, SUPPLY AND/OR USE

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.