1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gastazole 370 mg/g oral paste for horses [AT, CZ, DE, EL, ES, FR, HU, IE, IT, PL, PT, RO]
Gastazole vet 370 mg/g oral paste for horses [FI, SE, NO]
Gastazole vet [DK]
Omeprogard 370 mg/g oral paste for horses [BE, NL]

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)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

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

<{DD/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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gastazole 370 mg/g oral paste [AT, CZ, DE, , EL, ES, FR, HU, IE, IT, PL, PT, RO]
Gastazole vet 370 mg/g oral paste [FI, SE, DK, NO]
Omeprogard 370 mg/g oral paste [BE, NL]

2. STATEMENT OF ACTIVE SUBSTANCES

1 g paste contains 370 mg of Omeprazole

3. PACKAGE SIZE

1 syringe,
7 syringes,
10 syringes,
14 syringes,
20 syringes,
56 syringes,
72 syringes

4. TARGET SPECIES

Horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 1 day.

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

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.
Once opened, use by:

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

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

Chanelle Pharmaceuticals Manufacturing Ltd.,

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Label for Syringe}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gastazole [AT, CZ, DE, DK, EL, ES, FR, HU, IE, IT, PL, PT, RO]
Gastazole vet [FI, SE, DK, NO]
Omeprogard [BE, NL]

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Omeprazole 370 mg/g

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use by:

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Gastazole 370 mg/g oral paste for horses [AT, CZ, DE, DK, EL, ES, FR, HU, IE, IT, PL, PT, RO]
Gastazole vet 370 mg/g oral paste for horses [FI, SE, DK, NO]
Omeprogard 370 mg/g oral paste for horses [BE, NL]

2. Composition

1 g gram paste contains:

Active substance:
Omeprazole: 370 mg

Excipient:
Ferric Oxide Yellow (E172): 2 mg

Smooth homogeneous yellow to yellow-tan paste.

3. Target species

Horses.

4. Indications for use

For treatment of gastric ulcers and the prevention of recurrence 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 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.

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.

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.

7. 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 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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

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

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.

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

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. It is recommended to associate the treatment with changes of husbandry and training practices. Please see also “Special Warnings”.

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 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.

10. Withdrawal periods

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

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 30 ºC. Replace cap after use.
Shelf life after opening the immediate packaging: 28 days.
Do not use this veterinary medicinal product after the expiry date which is stated on the syringe and carton 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

Immediate package
Immediate packaging: Opaque white pre-filled oral syringe containing 7.57g 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.

15. Date on which the package leaflet was last revised

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.
Tel: +353 (0)91 841788
E-mail: vetpharmacoviggroup@chanellegroup.ie

Local representatives and contact details to report suspected adverse events:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information