PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{1 syringe, 7 Syringes, 14 syringes
Bulk box of 72 syringes}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GastroGard 370 mg/g oral paste

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each gram contains:

Omeprazole.....370 mg

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. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral route.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 1 day.

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

8. EXPIRY DATE

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

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C. 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

Boehringer Ingelheim Animal Health UK Ltd

14. MARKETING AUTHORISATION NUMBERS

Vm 08327/5027

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V (‘To be supplied only on veterinary prescription’)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Syringes}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GastroGard 370 mg/g oral paste

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

6.16 g of paste.
Per g: 370 mg omeprazole.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use by……

PACKAGE LEAFLET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GastroGard 370 mg/g oral paste for horses.

2. COMPOSITION

Each gram contains:

Active substance:
Omeprazole.....370 mg

Excipients:
Yellow Iron Oxide (E 172) .....2 mg

Smooth homogeneous yellow to yellow-tan paste.

3. TARGET SPECIES

Horses.

4. INDICATIONS FOR USE

Treatment and prevention of gastric ulcers in horses.

5. CONTRAINDICATIONS

Do not use in mares producing milk for human consumption.
Not recommended for animals under 4 weeks of age or weighing less than 70 kg bodyweight.

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.

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 and show the label/leaflet to the physician.

Persons developing a reaction after contact with the product should avoid handling the product in future.
Pregnancy and lactation:
Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic effect.
In the absence of data during pregnancy and lactation, the use of the veterinary medicinal product in pregnant and lactating mares is not recommended.

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.

Overdose:
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.

7. ADVERSE EVENTS

Horses:
None known.

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

For oral administration.
Veterinary medicinal 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 precautions for safe use in the target species”.

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

9. ADVICE ON CORRECT ADMINISTRATION

To deliver the veterinary medicinal 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.

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Shelf life after first opening the immediate packaging: 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.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. 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

Vm 08327/5027

Pack size:
Carton box of 1, 7 or 14 syringes
Bulk pack of 72 syringes
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Manufacturer responsible for the batch release:
Boehringer Ingelheim Animal Health France SCS
4, Chemin du Calquet
31000 Toulouse
France

Local representatives and contact details to report suspected adverse reactions:

United Kingdom (Great Britain)
Boehringer Ingelheim Animal Health UK Limited
Bracknell, RG12 8YS, UK
Tel: + 44 1344 746957

17. OTHER INFORMATION

Gavin Hall

Approved 25 October 2024