PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARTON & BUCKET LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Peptaleve 370 mg/g Oral Paste

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:

Active Substance: Omeprazole 370 mg

3. PACKAGE SIZE

1 x 7.59g oral syringe
7 x 7.59g oral syringes
72 x 7.59g oral syringes

4. TARGET SPECIES

Horses

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral Use

7. WITHDRAWAL PERIODS

Withdrawal period:
Horses: 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.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30^{o}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

Norbrook Laboratories Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 02000/4443

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGE UNITS
SYRINGE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Peptaleve

2. QUANTATIVE PARTCULARS OF THE ACTIVE SUBSTANCES

Each gram contains: Omeprazole 370 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {mm/yyyy}

Once opened use within 28 days.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Peptaleve 370 mg/g oral paste for horses

2. Composition

Each gram contains:

Active substance:
Omeprazole: 370 mg

Excipient:
Yellow Iron Oxide (E 172) 2 mg

A yellow to tan oily paste

3. Target species

Horses.

4. Indications for use

For the treatment and prevention of gastric ulcers.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or any of the excipients.

6. Special warnings

Special Warnings:
The veterinarian should consider the need for performing relevant diagnostic tests before selection of the treatment dose rate.

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 veterinary medicinal product may cause irritant and hypersensitivity reactions, avoid direct contact with skin and eyes. Use impervious gloves and do not eat or drink when handling and administering the veterinary medicinal 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 package leaflet or the label to the physician. Persons developing a reaction after contact with the veterinary medicinal product should seek medical advice and avoid handling the veterinary medicinal product in future.

Pregnancy and lactation:
Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic effect. The safety of the product has not been assessed during pregnancy and lactation. The use of the product is not recommended in pregnant and lactating mares.

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 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

None known.

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 using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

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 (1 division of the oral syringe/50 kg BW) 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 (1 division of the oral syringe/50 kg BW) is recommended.

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

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

Omeprazole 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.

To deliver Omeprazole at the dose of 4 mg Omeprazole /kg, set the oral syringe plunger to the appropriate dose division for the horse's weight. Each division on the oral syringe plunger delivers sufficient Omeprazole to treat 50 kg body weight. The contents of one oral syringe will treat a 700 kg horse at the rate of 4 mg Omeprazole per kg body weight.

To deliver Omeprazole at the dose of 1 mg Omeprazole /kg, set the oral syringe plunger to the dose division equivalent to one quarter of the horse's body weight. For example, to treat a horse weighing 400 kg, set the plunger to 100 kg. At this dose, each division on the oral syringe plunger will deliver sufficient Omeprazole to treat 200 kg body weight.

Replace cap after use.

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^{o}C.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.

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

Replace cap after use.

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

Vm 02000/4443

7 ml oral syringe containing 7.57 g of paste composed of polyethylene barrel, plunger and end cap, with polypropylene dosing rings.
Cartons of 1 or 7 oral syringes or buckets of 72 oral 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 and contact details to report suspected adverse reactions:

Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP
Northern Ireland
Tel: +44 (0)28 3026 4435
E-mail: phvdept@norbrook.co.uk

Manufacturer for the batch release:
Norbrook Laboratories Limited
105 Armagh Road
Newry
Co. Down, BT35 6PU
United Kingdom

17. Other information

POM - V

Gavin Hall
Approved: 08 May 2025