ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box 7 syringes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Omeproshield 370 mg/g oral paste

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:

Omeprazole .....370 mg

3. PACKAGE SIZE

7 x 6.16 g

4. TARGET SPECIES

Horses.

5. INDICATIONS

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 08327/3024

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

syringes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Omeproshield

2. 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 within 28 days.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Omeproshield 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

Prevention of gastric ulcers.

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. 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.
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. In the absence of data during pregnancy and lactation, the use of the 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 authorization 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

Prevention of gastric ulcers: one administration per day during 28 consecutive days at the dose rate of 1 mg omeprazole per kg body weight.

Oral administration.

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 use of the product with changes of husbandry and training practices. Please see also “Special precautions for safe use in the target species”.

9. Advice on correct administration

To deliver the 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 or household water.

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.

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 08327/3024

Pack size:
Immediate packaging: 10 ml syringe containing 6.16 g of paste composed of white polypropylene syringe barrel with a white LDPE cap, a rubber rod tip and a polypropylene plunger rod, with dose divisions calibrated by body weight.

Outer package and sales presentations:
- Carton box of 7 syringes

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:

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
UK

Manufacturer responsible for 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:

17. Other information

Pharmacodynamics
In studies lasting up to 28 days, treatment with the product at the dose rate of 1 mg omeprazole per kg body weight per day has been shown to help prevent the occurrence of gastric ulcers in horses exposed to ulcerogenic conditions.

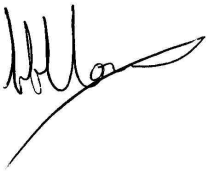
Omeprazole is a proton pump inhibitor belonging to the substituted benzimidazole class of compounds. It is an antacid, for treatment of peptic ulcers. Omeprazole suppresses gastric acid secretion by specific inhibition of the H^+/K^+-ATPase enzyme system at the secretory surface of the parietal cell. 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.

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 (Tmax) of approximately one hour after dosing. Mean peak concentration (Cmax) ranges from 385 ng/ml to 693 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 9 hours after treatment, and in urine as hydroxyomeprazole and O-desmethylomeprazole at 24 hours but not at 48 hours. 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 0.5 to 8 hours. After repeated oral administration, there is no evidence of accumulation.



Approved 11 May 2024