PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARTON BOX 7 SYRINGES}.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Omeproshield 370 mg/g oral paste for horses
Omeprazole

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each gram contains:

Active substance:
Omeprazole: 370 mg
Excipients:
Yellow Iron Oxide (E 172): 2 mg

3. PHARMACEUTICAL FORM

Oral paste.

4. PACKAGE SIZE

7x 6.16g syringes

5. TARGET SPECIES

Horses

6. INDICATION(S)

Treatment and prevention of gastric ulcers

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral route.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Horse:
Meat and offal: 1 day

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

9. SPECIAL WARNING(S), IF NECESSARY

Not recommended for animals under 4 weeks of age or weighing less than 70 kg bodyweight.

In the absence of data during pregnancy and lactation, the use of the product in pregnant and lactating mares is not recommended.

User warnings: read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 28 days.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read the package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4263

VPA10454/071/001

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SYRINGES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Omeproshield 370 mg/g oral paste for horses
Omeprazole

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

370 mg/g

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

6.16 g of paste

4. ROUTE(S) OF ADMINISTRATION

Oral route

5. WITHDRAWAL PERIOD

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

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached, use by:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

PACKAGE LEAFLET

Omeproshield 370 mg/g oral paste for horses

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS
4, Chemin du Calquet
31300 Toulouse
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Omeproshield 370 mg/g oral paste for horses
Omeprazole

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each gram contains:

Active substance:
Omeprazole: 370 mg

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

Smooth homogeneous yellow to yellow-tan paste.

4. INDICATION(S)

Treatment and 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. ADVERSE REACTIONS

There are no known treatment-related clinical adverse effects.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon

7. TARGET SPECIES

Horses.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

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 the treatment with changes of husbandry and training practices. Please see also “Special Precautions for Use”.

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 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 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 PERIOD

Horse :
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 after the expiry date stated on the label after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each 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 for use in animals:
None

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. Use impervious gloves and 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
Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic effect.
In the absence of data during pregnancy, the use of the product in pregnant mares is not recommended.

Lactation
In the absence of data during lactation, the use of the product in 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 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Any unused product or waste material should be disposed of in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pharmacodynamic properties
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.

Pharmacokinetic properties
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.

Package size:
Carton box of 7 syringes

Keep out of the sight and reach of children.

Approved 28 May 2020