LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton Box & Bucket labelling

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ulcergold 370 mg/g Oral Paste for Horses

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Omeprazole 370 mg/g

3. PHARMACEUTICAL FORM

Oral Paste

4. PACKAGE SIZES

1 oral syringe
7 oral syringes
72 oral syringes

5. TARGET SPECIES

Horses

6. INDICATION(S)

For treatment and prevention of gastric ulcers in horses.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral Use
Read the package leaflet before use

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Horses: Meat and offal: 1 day.

9. SPECIAL WARNING(S), IF NECESSARY

Not recommended for animals under 4 weeks of age or weighing less than 70 kg bodyweight.
The use of Omeprazole in pregnant or lactating mares is not recommended.
Risk of irritant and hypersensitivity reactions.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 28 days
Once broached/opened, use by: _____.

11. SPECIAL STORAGE PRECAUTIONS

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 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

POM - V Prescription Only Medicine – Veterinarians.

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

(EU)
Norbrook Laboratories (Ireland) Limited

Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Ltd
Station Works
Newry
Co. Down
BT35 6JP

16. MANUFACTURER'S AUTHORISATION NUMBER(S)

VM 02000/4390

17. MANUFACTURER'S BATCH NUMBER

BN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Oral Syringe labelling

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ulcergold 370 mg/g Oral Paste for Horses

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Omeprazole 370 mg/g

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER

7.57g of oral paste

4. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use

5. WITHDRAWAL PERIOD(S)

Horse: Meat and offal: 1 day

6. BATCH NUMBER

BN {number}

7. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the immediate packaging: 28 days
Once broached/opened, use by: _____.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For Animal Treatment Only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

PEPTIZOLE 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:
(EU)
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Ltd
Station Works
Newry
Co. Down
BT35 6JP

Manufacturers responsible for batch release:
Norbrook Laboratories Limited
105 Armagh Road
Newry, Co. Down, BT35 6PU
Northern Ireland

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry, Co. Down, BT35 6JP
Northern Ireland

Norbrook Manufacturing Ltd.
Rossmore Industrial Estate
Monaghan
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ulcergold 370 mg/g Oral Paste for Horses

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

Each gram contains:
Omeprazole: 370 mg

Yellow Iron Oxide (E 172): 2 mg

A yellow to tan oily paste

4. INDICATION(S)

For treatment and prevention of gastric ulcers in horses.

5. CONTRAINDICATIONS

Not recommended for animals under 4 weeks of age or weighing less than 70 kg bodyweight.
The use of Omeprazole in pregnant or lactating mares is not recommended.
Do not use in cases of hypersensitivity to the active substance or any of the excipients.

6. ADVERSE REACTIONS

There are no known treatment-related clinical adverse effects.
In cases of hypersensitivity reactions, treatment should be discontinued immediately.
If you notice any side effects or you think this medicine has not worked, please inform your veterinary surgeon.
Alternatively you can report via your national reporting system.

7. TARGET SPECIES

Horses**.**

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

For oral 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 (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 section 12

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.

For oral 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 (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 WARNING(S).

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

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 PERIOD(S)

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^{o}C
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and oral syringe after "EXP".
Shelf life after first opening the container: 28 days

Replace cap after use.

12. SPECIAL WARNING(S)

Special precautions for use in animals
The veterinarian should consider the need for performing relevant diagnostic tests before selection of the treatment dose rate.

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.

User Warnings:
As this 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 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 seek medical advice and avoid handling the product in future.

Use during pregnancy, lactation or lay
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.

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 MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon/pharmacist how to dispose of medicines no longer required.
These measures should help to protect the environment

14. DATE ON WHICH THE PACKAGE INSERT WAS LAST REVISED

November 2021

15. OTHER INFORMATION

The oral paste is available in the following pack sizes:
- 1 carton box containing 1 oral syringe
- 1 carton box containing 7 oral syringes
- Bucket containing 72 oral syringes

Not all pack sizes may be marketed

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

Distributed by:

For animal Treatment Only.

POM - V Prescription Only Medicine – Veterinarians.

Approved: 22/12/21