A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equizol 400 mg gastro-resistant granules for horses

2. STATEMENT OF ACTIVE SUBSTANCES

1 sachet contains 400 mg of omeprazole

3. PHARMACEUTICAL FORM

Gastro-resistant granules.

4. PACKAGE SIZE

14 x 5g
28 x 5g
56 x 5g
84 x 5g
100 x 5g
112 x 5g
200 x 5g

5. TARGET SPECIES

Horses

6. INDICATION(S)

For treatment of gastric ulcers in horses.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD (S)

Withdrawal period(s):
Meat and offal: 2 days
Not authorised for use in animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Not applicable.

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.

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

CP-Pharma Handelsges. mbH
Ostlandring 13
31303 Burgdorf
Germany

16. MARKETING AUTHORISATION NUMBER

Vm 20916/4023

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Sachet foil

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equizol 400 mg gastro-resistant granules for horses

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Omeprazole – 400 mg per sachet

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

5g

4. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period:
Meat and offal: 2 days
Not authorised for use in animals producing milk for human consumption.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Equizol 400 mg gastro-resistant granules 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 and manufacturer responsible for batch release:
CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equizol 400 mg gastro-resistant granules for horses

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

Omeprazole 400 mg per 5 g sachet.

Gastro-resistant granules.
White to beige spherical granules.

4. INDICATION(S)

For treatment of gastric ulcers in horses.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

None known.

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 inform your veterinary surgeon.

7. TARGET SPECIES

Horses.

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

For oral administration.

Treatment of gastric ulcers:
One administration of 2 mg omeprazole per kg body weight per day for 28 consecutive days.

Each sachet contains sufficient omeprazole to treat 200 kg body weight. Sachets should not be subdivided. Therefore, calculate the dose required (2 mg/kg per day) and round up to the nearest 200 kg increment. Mix the appropriate number of whole sachets into a small amount of the horse's feed. This product may only be added to dry feed and the feed should not be dampened.

Body weight range (kg)	**125-200**	**201-400**	**401-600**	**601-800**
Number of sachets	**1**	**2**	**3**	**4**

It is recommended to associate the treatment with changes of husbandry and training practices.

9. ADVICE ON CORRECT ADMINISTRATION

See section 8.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 2 days

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 use this veterinary medicinal product after the expiry date which is stated on the sachet and carton after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

As the safety of the product has not been assessed in foals under 8 months of age or weighing less than 125 kg bodyweight, the use of the product is not recommended in these animals.

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:

This product may cause adverse gastrointestinal effects or hypersensitivity (allergic) reactions if accidentally ingested, particularly by children.
Do not eat or drink whilst handling or administering the product.
Wash hands or any exposed skin after use.
Any part-used sachets should be returned to the original carton and suitably stored to prevent access by children.
In case of accidental ingestion, especially by a child, seek medical advice if symptoms persist.

Use during pregnancy, lactation or lay:

Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic effect with omeprazole.

The safety of the veterinary medicinal product has not been established during pregnancy and lactation in the target species; use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Omeprazole may delay the elimination of warfarin. Interaction with drugs metabolised by liver enzymes cannot be excluded.

Omeprazole may potentially alter benzodiazepine metabolism and prolong CNS effects.

Clarithromycin may increase levels of omeprazole.

Omeprazole may reduce cyclosporine metabolism.

Omeprazole may decrease absorption of the drugs requiring decreased gastric pH for optimal absorption (ketoconazole, itraconazole, iron, ampicillin esters).

Overdose (symptoms, emergency procedures, antidotes):

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.

Major incompatibilities:

Not applicable.

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

Medicines should not be disposed of via wastewater. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

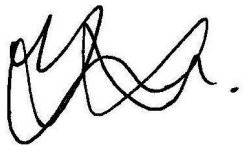
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

[To be completed nationally] <DD/MM/YYYY>

15. OTHER INFORMATION

Not all pack sizes may be marketed.

Sachets containing 5 g of granules in following pack sizes:
- Carton box containing 14 sachets.
- Carton box containing 28 sachets.
- Carton box containing 56 sachets.
- Carton box containing 84 sachets.
- Carton box containing 100 sachets.
- Carton box containing 112 sachets.
- Carton box containing 200 sachets.



Approved: 17 August 2022