

**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
Omeprazole

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.