1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equizol 400 mg gastro-resistant granules for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet of 5 g contains:

Active substances:

Omeprazole 400 mg

Excipients:

Qualitative composition of excipients and other constituents
<u>Omeprazole gastro-resistant granules:</u>
Sugar spheres
Talc
Lactose
Sodium laurilsulfate
Disodium phosphate dodecahydrate
Sodium starch glycolate (Type A)
Hypromellose
Titanium dioxide
Methacrylic acid – ethyl acrylate copolymer (1:1)
Triethyl citrate
<u>Flavoured granules:</u>
Sugar spheres
Apple flavour
Talc
Hypromellose
Triethyl citrate

White to beige spherical granules

3. CLINICAL INFORMATION

3.1 Target species

Horses

3.2 Indications for use for each target species

For treatment of gastric ulcers in horses.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
See section 3.5.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

As the safety of the veterinary medicinal product has not been assessed in foals under 8 months of age or weighing less than 125 kg bodyweight, the use of the veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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 and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses:

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy and lactation:

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects.
Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 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).

3.9 Administration routes and dosage

Oral use.

Treatment of gastric ulcers:
One administration of 2 mg omeprazole/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 omeprazole/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 veterinary medicinal 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. See section 3.5.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QA02BC01

4.2 Pharmacodynamics

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.
The full effect on the inhibition of acid secretion is reached by five days after the first administration.

4.3 Pharmacokinetics

The absorption of omeprazole after oral administration as gastro resistant granules is rapid with time to maximum plasma concentrations (T_{max}) of approximately one hour after dosing. Mean peak concentration (C_{max}) is approximately 236.7 ng/ml after dosing with 2 mg/kg. There is a significant first-pass effect following oral administration. Omeprazole is rapidly metabolised principally into glucuronides of demethylated and hydroxylated omeprazole sulphide (urinary metabolites) and methyl sulphide omeprazole (biliary metabolite) as well as into reduced omeprazole (both). After oral administration at 2 mg/kg, omeprazole is detectable in plasma for 8 hours after treatment. 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 0.4 to 2.8 hours.
After repeated oral administration, there is no evidence of accumulation.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Sachets
Polyethylene / aluminium / paper sachets containing 5 g of granules per sachet.

Pack sizes:
Carton box containing 14, 28, 56, 84, 100, 112 or 200 sachets.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

CP- Pharma Handelsgesellschaft mbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10810/014/001

8. DATE OF FIRST AUTHORISATION

20/07/2018

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

05/12/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).