

[Version 9.1,11/2024]

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equizol 400 mg gastro-resistant granules for horses (AT, BE, CZ, DE, ES, FR, HU, IE; IT, NL, PL, PT, SK, UK)

Hippozol vet 400 mg gastro-resistant granules for horses (FI, NO, SE, DK)

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)**8. DATE OF FIRST AUTHORISATION**

Date of first authorisation: DD/MM/YYYY

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

MM/YYYY

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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equizol 400 mg gastro-resistant granules

2. STATEMENT OF ACTIVE SUBSTANCES

Each sachet contains 400 mg of omeprazole

3. PACKAGE SIZE

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

4. TARGET SPECIES

Horses

Or instead of written text:



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: 2 days

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

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsges. mbH

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Sachet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equizol



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

400 mg omeprazole/sachet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Equizol 400 mg gastro-resistant granules for horses

2. Composition

Each sachet of 5 g contains:

Active substances:

Omeprazole 400 mg

White to beige spherical granules

3. Target species

Horses.

If pictograms are included on the labelling



4. Indications for use

For treatment of gastric ulcers in horses.

5. Contraindications

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

6. Special warnings

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.

Pregnancy and lactation:

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

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:

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.

7. Adverse events

Horses:

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system:

8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

See section "Dosage for each species, routes and method of administration".

10. Withdrawal periods

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.

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

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 precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Sachets containing 5 g of granules in following pack sizes:

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

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

MM/YYYY

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

16. Contact details

Marketing authorisation holder <,> <and> <manufacturer responsible for batch release> <and contact details to report suspected adverse events>:

CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany
Tel: +49-(0)5136-6066-0

Local representatives and contact details to report suspected adverse events:

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