# SUMMARY OF PRODUCT CHARACTERISTICS

## 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 substance:**
Omeprazole 400 mg.

For the full list of excipients, see section 6.1

## 3. PHARMACEUTICAL FORM

Gastro-resistant granules
White to beige spherical granules

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Horses

### 4.2 Indications for use, specifying the target species

For treatment of gastric ulcers in horses.

### 4.3 Contraindications

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

See section 4.5.

### 4.4 Special warnings for each target species

None.

### 4.5 Special precautions for use

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.

## 4.6 Adverse reactions (frequency and seriousness)

There are no known treatment-related clinical adverse effects.

## 4.7 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.

## 4.8 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).

## 4.9 Amounts to be administered and administration route

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. See section 4.5.

### 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

### 4.11 Withdrawal period(s)

Meat and offal: 2 days

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

## 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: drugs for peptic ulcers and gastro-oesophageal reflux disease (GORD), Proton pump inhibitors.
ATCvet code: QA02BC01.

### 5.1 Pharmacodynamic properties

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.

### 5.2 Pharmacokinetic particulars

The absorption of omeprazole after oral administration as gastro resistant granules is rapid with time to maximum plasma concentrations (Tmax) of approximately one hour after dosing. Mean peak concentration (Cmax) 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.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Omeprazole gastro-resistant granules
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

Flavoured granules
Sugar spheres
Apple flavour
Talc
Hypromellose
Triethyl citrate

### 6.2 Major incompatibilities

Not applicable.

### 6.3 Shelf life

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

### 6.4 Special precautions for storage

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

### 6.5 Nature and composition of immediate packaging

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

**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.

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

## 8. MARKETING AUTHORISATION NUMBER

Vm 20916/4023

## 9. DATE OF FIRST AUTHORISATION

17 July 2018

## 10. DATE OF REVISION OF THE TEXT

April 2019

Approved: 10 April 2019

D Austin