

For the use only of a Registered Veterinary Practitioner or a Hospital or a Laboratory or a Farm.

Omeprazole Oral Paste 37% w/w
Kick-ULCER®
Oral Paste

COMPOSITION:

Each gm contain:
Omeprazole BP 370 mg

INDICATIONS:

For treatment of gastric ulcers and the prevention of recurrence of gastric ulcers.

DOSEAGE AND ADMINISTRATION:

Treatment of gastric ulcers: The recommended dose rate is 4 mg Omeprazole /kg body weight. Initially one administration per day during 28 consecutive days at the dose rate of 4 mg Omeprazole /kg body weight followed immediately by a dosage regimen of one administration per day during 28 consecutive days at the dose rate of 1 mg Omeprazole/kg body weight, to reduce the recurrence of gastric ulcers during treatment. Should recurrence occur, re-treatment at a dose rate of 4 mg Omeprazole /kg body weight is recommended.

Prevention of recurrence of gastric ulcers: One administration per day at the dose rate of 1 mg Omeprazole / kg body weight.

DIRECTIONS FOR USE:

For oral administration.

To deliver Omeprazole at the dose of 4 mg Omeprazole /kg, set the oral syringe plunger to the appropriate dose division for the horse's weight. Omeprazole paste for horses is recommended for use in horses and foals, 4 weeks of age and older.

The contents of one syringe will dose 1,250 lb (568 kg) horse at the rate of 1.8 mg omeprazole/lb body weight (4 mg/kg). For treatment of gastric ulcers, each weight marking on the syringe plunger will deliver sufficient omeprazole to treat 250 lb (114 kg) of body weight, for prevention of recurrence of gastric ulcers, each weight marking will deliver sufficient omeprazole to dose 500 lb (227 kg) of body weight. To deliver omeprazole paste at the treatment dose rate of 1.8 mg/lb body weight (4 mg/kg), set the syringe plunger to the appropriate weight marking according to the horse's weight in pounds.

To deliver omeprazole paste at the dose rate of 0.9 mg/lb (2 mg/kg) to prevent recurrence of ulcers, set the syringe plunger to the appropriate weight marking according to the horse's weight in pounds. To set the syringe plunger, unlock the knurled ring by rotating it one-fourth turn, slide the knurled ring along the plunger shaft so that the side nearest the barrel is at the appropriate notch. Rotate the plunger ring one-fourth turn to lock it in place and ensure it is locked. Make sure the horse's mouth contains no feed, remove the cover from the lip of the syringe, and insert the syringe into the horse's mouth at the interdental space. Depress the plunger until stopped by the knurled ring. The dose should be deposited on the back of the tongue or deep into the cheek pouch. Care should be taken to ensure that the horse consumes the complete dose. Treated animals should be observed briefly after administration to ensure that part of the dose is not lost or rejected. If any of the dose is lost, re-dosing is recommended.

If, after dosing, the syringe is not completely empty, it may be reused on, following days until emptied, replace the cap after each use.

TARGET SPECIES:

Horses & Foals.

PHARMACOLOGICAL PROPERTIES:

Pharmacotherapeutic group: Drugs for acid related disorders, Proton pump inhibitors

ATC Vet code: QA02BC01

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. At 8, 16 and 24 hours after dosing horses with Omeprazole at 4 mg/kg/day orally, pentagastrin-stimulated gastric acid secretion was inhibited by 99%, 95% and 90% and basal secretion was inhibited by 99%, 90% and 83%. The full effect on the inhibition of acid secretion is reached by five days after the first administration.

PHARMACOKINETICS:

The median bioavailability of Omeprazole after oral administration as a paste is 10.5% (range 4.1 to 12.7%). The absorption is rapid with time to maximum plasma concentrations (T_{max}) of approximately 1.25 hours after dosing. C_{max} values for individual animals ranged between 121 ng/ml and 1470 ng/ml after one administration of the product at 4 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 4 mg/kg, Omeprazole is detectable in plasma for 9 hours after treatment and in urine as hydroxy Omeprazole and O-desmethyl Omeprazole at 24 hours but not at 48 hours. 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 0.5 to 8 hours. After repeated oral administration, there is no evidence of accumulation.

WARNING & PRECAUTIONS:

Special precautions for use in animals:

- Not recommended for animals under 4 weeks of age or weighing less than 70 kg body-weight.
- 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 wellbeing 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:

- Wear gloves during application.
- Wash the hands thoroughly after use.
- Do not eat, drink or smoke while handling this product.
- Assess bodyweight as accurately as possible before calculating the dosage.
- In case of accidental eye contact, rinse immediately with plenty of water.
- In case of accidental ingestion or eye irritation, seek medical advice and show the package leaflet or label to the physician.

CONTRAINDICATIONS:

Hypersensitivity to any of the Ingredients.

Not permitted for use in mares producing milk for human consumption.

ADVERSE EFFECTS:

There are no known treatment-related clinical adverse effects.

In cases of hypersensitivity reactions, treatment should be discontinued immediately.

PREGNANCY AND LACTATION:

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

In the absence of data during pregnancy and lactation, the use of the Omeprazole Paste is not recommended

OVERDOSAGE:

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 were observed following daily use for 21 days at an Omeprazole dosage of 40 mg/kg in adult horses.

WITHDRAWAL PERIOD:

Horse: Meat and offal: 1 day

STORAGE:

Store below 30°C.

Discard after 6 months from the date of the first use.

PRESENTATION:

6.15gms syringe packed in a Primary Carton along with the Pack Insert.

**VETERINARY
FOR ANIMAL TREATMENT ONLY.
NOT FOR HUMAN USE.
FOR EXTERNAL APPLICATION ONLY.**

SHAKE WELL BEFORE USE.

KEEP OUT OF REACH OF CHILDREN & PETS, AWAY FROM FOOD.

Carefully read the accompanying instructions before use.

Veko®

Manufactured & Marketed by:
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