GastroGard Paste (omeprazole) Oral Paste for Equine Horses

Indications

- GastroGard Paste for horses is recommended for use in horses and foals 4 weeks of age and older. The contents of one syringe will dose a 1250 lb (568 kg) horse at the rate of 1.8 mg omeprazole/lb body weight (4 mg/kg). For the prevention of recurrence of gastric ulcers, continue treatment for at least an additional 4 weeks by administering GastroGard Paste at the recommended daily maintenance dose of 0.9 mg/lb (2 mg/kg).

Directions for Use

- To deliver GastroGard Paste at the dose rate of 0.9 mg/lb (2 mg/kg) to prevent recurrence of ulcers, set the syringe plunger to the weight marking corresponding to half of the horse’s weight in pounds.

- To deliver GastroGard Paste at the dose rate of 1.8 mg omeprazole/lb body weight (4 mg/kg), set the syringe plunger to the appropriate weight marking according to the horse’s weight in pounds.

- To set the syringe plunger:
  1) While holding plunger, turn the knurled ring on the plunger ¼ turn to the left and slide the knurled ring along the plunger shaft so that the side nearest the barrel is at the appropriate weight marking, aligning the arrows on the ring and plunger as shown in the pictogram.
  2) Lock the ring in place by making ½ turn to the right. Ensure it is locked.

- Make sure the horse’s mouth contains no feed. Remove the cover from the tip 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 the dose is not lost or rejected. If any of the dose is lost, redosing 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.

Warning

- Do not use in horses intended for human consumption. Keep this and all drugs out of the reach of children. In case of ingestion, contact a physician. Physicians may contact a poison control center for advice concerning accidental ingestion.

Adverse Reactions

- In efficacy trials, when the drug was administered at 1.8 mg omeprazole/lb (4 mg/kg) body weight daily for 28 days and 0.9 mg omeprazole/lb (2 mg/kg) body weight daily for 30 additional days, no adverse reactions were observed.

Precautions

- The safety of GastroGard Paste has not been determined in pregnant or lactating mares.

Clinical Pharmacology

- The mechanism of Action: Omeprazole is a gastric acid pump inhibitor that regulates the final step in hydrogen ion production and blocks gastric acid secretion regardless of the stimulus. Omeprazole irreversibly binds to the gastric parietal cell’s H+, K+ ATPase enzyme which pumps hydrogen ions into the lumen of the stomach in exchange for potassium ions. Since omeprazole accumulates in the cell cannaliculi and is irreversibly bound to the effect site, the plasma concentration at steady state is not directly related to the amount that binds to the enzyme. The relationship between omeprazole action and plasma concentration is a function of the rate-limiting process of H+, K+ ATPase activity/turnover. Once all of the enzyme becomes bound, acid secretion resumes only after new H+, K+ ATPase is synthesized in the parietal cell (i.e., the rate of new enzyme synthesis exceeds the rate of inhibition).

- Pharmacokinetics: In a pharmacokinetic study involving thirteen healthy, mixed breed horses (8 female, 5 male) receiving multiple doses of omeprazole paste (1.8 mg/lb once daily for fifteen days) in either a fed or fasted state, there was no evidence of drug accumulation in the plasma when comparing the extent of systemic exposure (AUC0-∞). When comparing the individual bioavailability data (AUC0-∞, Cmax, and Tmax measurements) across the study days, there was great inter- and intra-animal variability in the rate and extent of product absorption. Also, the extent of omeprazole absorption in horses was reduced by approximately 67% in the presence of food. This is evidenced by the observation that the mean AUC0-∞ values measured during the fifth day of omeprazole therapy when the animals were fasted for 24 hours was approximately three times greater than the AUC estimated after the first and fifteenth doses when the horses were fed hay ad libitum and sweet feed (grain) twice daily. Prandial status did not affect the rate of drug elimination. The terminal half-life estimates (N-38) ranged from approximately one-half to eight hours.

Efficacy

- In an efficacy study in horses with gastric cannuae, secretion of gastric acid was inhibited in horses given 4 mg omeprazole/kg/day. After the expected maximum suppression of gastric acid secretion was reached (5 days), the actual secretion of gastric acid was reduced by 98%, 95% and 90% at 8, 16, and 24 hours, respectively.

- In a placebo controlled tolerance study, adult horses were treated with GastroGard Paste or a placebo and then given a challenge dose of omeprazole (2 mg/kg) at 24 hours. No adverse reactions attributable to omeprazole treatment were noted.

- In a male reproductive safety study, 10 stallions received GastroGard Paste at 12 mg/kg/day (3x the recommended dose) for 91 days. Subsequent daily administration of GastroGard Paste to provide omeprazole at 0.9 mg/lb (2 mg/kg) for 30 days prevented recurrence of gastric ulcers in 84% of treated horses, whereas ulcers recurred or became more severe in horses removed from omeprazole treatment.

Diagnostic and Management Considerations: The following clinical signs may be associated with gastric ulceration in adult horses: inappetance or decreased appetite attributable to omeprazole treatment were noted.

- The safety of administration of GastroGard Paste for longer than 91 days has not been determined. Maximal acid suppression occurs after three to five days of treatment with omeprazole.

Safety

- GastroGard Paste was well tolerated in the following controlled efficacy and safety studies.

- In field trials involving 139 horses, including foals as young as one month of age, no adverse reactions attributable to omeprazole treatment were noted.

- In a placebo controlled adult horse safety study, horses received 20 mg/kg/day omeprazole (5x the recommended dose) for 90 days. No treatment related adverse events were observed.

- In a placebo controlled tolerance study, adult horses were treated with GastroGard Paste at a dosage of 40 mg/kg/day (10x the recommended dose) for 21 days. No treatment related adverse effects were observed.

- A placebo controlled faecal safety study evaluated the safety of omeprazole at doses of 4, 12 or 20 mg/kg (1, 3 or 5x) once daily for 91 days. Foals ranged in age from 86 to 110 days at study initiation. Gamma glutamyltransferase (GGT) levels were significantly elevated in horses treated at exaggerated doses of 20 mg/kg (5x the recommended dose). Mean stomach to body weight ratio was higher for foals in the 3x and 5x groups than for controls; however, no abnormalities of the stomach were evident on histological examination.

Reproducitve Safety

- In a male reproductive safety study, 10 stallions received GastroGard Paste at 12 mg/kg/day (3x the recommended dose) for 70 days. No treatment related adverse effects on semen quality or breeding behavior were observed. A safety study in breeding mares has not been conducted.

For More Information

- Please call 1-888-637-4251.
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