GASTROGARD® (omeprazole)

Oral Paste for Horses and Foals
NADA 1H - 12L, Approved by FDA

Gastric Ulcers: ULCERGARD is effective in horses that are not currently suffering from an acute episode of gastric ulceration.

For treatment of gastric ulcers, GASTROGARD Paste should be administered orally once-a-day for 4 weeks at the recommended maintenance dose of 0.9 mg omeprazole/lb (2 mg/kg). For prevention of recurrence of gastric ulcers, each weight marking will deliver sufficient omeprazole to treat 250 lb (114 kg) body weight. For prevention of recurrence of gastric ulcers, each weight marking will deliver sufficient omeprazole to dose 0.9 mg/lb (2 mg/kg).

For treatment and prevention of recurrence of gastric ulcers in horses and foals 4 weeks of age and older.

Dosage Regimen

For treatment of gastric ulcers, 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 150 lb (68 kg) horse at the rate of 1.8 mg omeprazole/lb body weight (3 mg/kg). For treatment of gastric ulcers, each weight marking on the syringe plunger will deliver sufficient omeprazole to treat 250 lb (114 kg) body weight. For prevention of recurrence of gastric ulcers, each weight marking will deliver sufficient omeprazole to dose 0.9 mg/lb (2 mg/kg).

Directions for Use

GASTROGARD Paste for horses is recommended for use in horses and foals 4 weeks of age and older. A placebo controlled foal safety study evaluated the safety of omeprazole at doses of 4, 12 or 20 mg/kg (1X, 3X or 5X the recommended dose) in 38 foals. GASTROGARD Paste was well-tolerated in the following controlled efficacy and safety studies.

- **Efficacy:**
  - In field trials involving 199 horses, including foals as young as one month of age, no adverse reactions attributable to omeprazole therapy were noted.
  - In placebo controlled adult horse safety study, horses received 20 mg/kg/day of omeprazole (5X the recommended dose) for 90 days. No treatment-related adverse effects were observed.
  - In placebo controlled balanced diet study, all horses were treated with GASTROGARD Paste at a dosage of 40 mg/kg/day (10X the recommended dose) for 21 days. Horses readily accepted GASTROGARD Paste and no treatment-related adverse effects were observed.

- **Safety:**
  - GASTROGARD Paste was used for treatment of more than 91 horses for more than 30 days in commercial trials, horses readily accepted GASTROGARD Paste at 1.8 mg omeprazole/lb (4 mg/kg) daily for 28 days, effectively healed and reduced the severity of gastric ulcers in 92% of treated horses. In comparison, 32% of controls exhibited healed or less severe lesions. Horses enrolled in the study were healthy animals confirmed to have gastric ulcers by gastroscope. Subsequent daily administration of GASTROGARD Paste to provide omeprazole at 0.9 mg/lb (2 mg/kg) for 30 days prevented recurrence of gastric ulceration in 84% of treated horses, whereas ulcer lesions in 38% of horses remained unhealed.

Gastric ulcers may recur in horses if therapy to prevent recurrence is not administered after the initial treatment is completed. Use GASTROGARD Paste at 0.9 mg omeprazole/lb body weight (2 mg/kg) to prevent gastric ulcers following treatment. The safety of administration of GASTROGARD Paste for longer than 91 days has not been determined.

Ingestion of GASTROGARD Paste may be followed by mild stomach upset in some horses. Do not exceed recommended dose in horses. Do not use in horses intended for human consumption. Keep this and all medicine out of the reach of children.

GASTROGARD Paste has not been determined to be carcinogenic or mutagenic.

**Precautions**

- Gastric ulcers may recur in horses if therapy to prevent recurrence is not administered after the initial treatment is completed.
- GASTROGARD Paste was well-tolerated in the following controlled efficacy and safety studies.
- In field trials involving 199 horses, including foals as young as one month of age, no adverse reactions attributable to omeprazole therapy were noted.
- In placebo controlled adult horse safety study, horses received 20 mg/kg/day of omeprazole (5X the recommended dose) for 90 days. No treatment-related adverse effects were observed.
- In placebo controlled balanced diet study, all horses were treated with GASTROGARD Paste at a dosage of 40 mg/kg/day (10X the recommended dose) for 21 days. Horses readily accepted GASTROGARD Paste and no treatment-related adverse effects were observed.
- In placebo controlled field safety study evaluated the safety of omeprazole at doses of 12 or 20 mg/kg (33x or 5x) once daily for 91 days. Horses formed a group from ages 6 to 115 days at study initiation. Gastric-glandular histopathology (GSH) levels were significantly elevated in horses treated at increased doses of 25 mg/kg (5x the recommended dose). Mean stomach to body weight ratio was higher for flax in the 3X and 5X groups than for controls; however, no abnormalities of the stomach were evident on histological examination.

**Reproductive Safety**

In a non-reproductive safety study, 10 stallions received GASTROGARD Paste at 12 mg/kg (3X the recommended dose) for 70 days. Horses treated with 12 mg/kg of omeprazole were observed for semen quality or breeding behavior were observed. A semen study in breeding mares has not been conducted.

For More Information

Please call 1-888-637-4251 and please visit our Web site at www.gastrogard.com. Merial Limited, a company limited in Delaware, USA as Merial LLC.

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