

## When Something Just Isn't Right

*Gastroscopy and fecal egg count tests can provide answers.*

You know your horse, so if his behavior or appearance should suddenly change, even in subtle ways, you may recognize it. But what's causing those changes?

A few months after Prairie Village, Kan., resident Linda Powers purchased her new horse, Starched And Pressed, also known as Cosmo, she tried to figure him out.

"We took our time to get to know Cosmo," Powers says of her AQHA-Appendix 10-year-old gelding. "We worked to figure out what feed and hay he liked, and what made him happy and what didn't. He had lost a little weight, and we were doing everything we could to get him as healthy as possible."

### Coming to a Diagnosis

A few months after purchasing the big bay gelding, Powers noticed he was growing long hair, despite the fact that it was late spring and all of the other horses in the barn had already shed their winter coats. He was still a little skinny, as well.

Thinking about Cosmo's signs, Powers considered deworming. Horses with worms often have poor hair coats and poor body condition,<sup>1</sup> the same signs that could also point to ulcers.<sup>2</sup> These two common clinical signs have the potential to lead to a multitude of diagnoses, even beyond worms or ulcers.

Next, Powers contacted her veterinarian who tested him for parasites and ruled out other possible causes before determining he needed to be treated for stomach ulcers. The veterinarian based the diagnosis on recent changes in Cosmo's life – moving to a new barn with a new owner – and signs of poor hair coat and poor body condition. "By that time, it was summer, and despite deworming, Cosmo still had a long hair coat," Powers says.

To treat the suspected ulcers, her veterinarian recommended GASTROGARD® (omeprazole), the only proven and FDA-approved ulcer product that effectively reduces acid, allowing the stomach to heal itself without removing the horse from training or competing.<sup>2</sup>

"Right after our veterinarian made the recommendation, I found a [podcast about](#)



Alecia McAtee, DVM, helps perform a gastroscopic exam on Cosmo.

[ulcers](#) and learned so much,” Powers says. “We started treatment right away.”

Powers thought it was interesting that prior to being diagnosed with ulcers, when Cosmo received regular chiropractic adjustments including palpation of points that could indicate stomach ulcers, the chiropractor thought Cosmo did not have ulcers. While chiropractic can be useful, gastroscopy is the only way to definitively diagnose and grade equine stomach ulcers.<sup>3</sup>

### **Treatment and Prevention**

After treatment with GASTROGARD, Powers worked with another veterinarian who performed a gastroscopic exam on Cosmo to determine the progress of his treatment and they were excited to hear his stomach showed no signs of ulcers.

Now that Powers knows Cosmo is prone to stomach ulcers, she works to prevent them. She gives Cosmo ULCERGARD® (omeprazole) during periods of stress, such as training and trailering, as it is the only proven and FDA-approved prevention.<sup>4</sup>

“We use a slow-feed hay net to mimic a more natural grazing situation,” Powers says. “With the veterinarian’s recommendations, we keep him on SmartGut® Ultra Pellets and give him ULCERGARD anytime there’s a new horse in his paddock, every time we haul him and when we show.”

For deworming, Powers also has her veterinarian perform a fecal egg count test (FECT) in the spring and fall to determine a course of treatment, if needed.

### **Follow Veterinarian Recommendations**

Powers says having the veterinarian perform a gastroscopy was of great value. She’s also thankful for other diagnostic tools, like the FECT. “Veterinarians have all of these tools in their toolbox; it’s so great that they can figure out what’s going on with your horse,” says Powers.

When it comes to deworming, according to the AAEP, [establishing an effective parasite control program is ranked as one of the most important management practices](#) next to supplying your horse with clean water and high-quality feed.<sup>1</sup> Whether or not symptoms are evident, the AAEP guidelines recommend getting a FECT from a sample of fresh manure, which a veterinarian will then examine under a microscope before recommending a deworming program.

Parasite control means better overall horse health, so if parasites are present, the answer is to [treat them with ZIMECTERIN® Gold \(ivermectin and praziquantel\)](#), the #1 selling broad-spectrum dewormer.<sup>5</sup>

Some diseases present obvious clinical signs while others are harder to detect. Early intervention and treatment are the keys to keeping your horse healthy. This is why it is important to contact your veterinarian as soon as you notice, “something just isn’t right.”

**IMPORTANT SAFETY INFORMATION:**

*ULCERGARD can be used in horses that weigh at least 600 pounds. Safety in pregnant mares has not been determined.*

*Caution: Safety of GASTROGARD in pregnant or lactating mares has not been determined.*

**ZIMECTERIN GOLD: Not for use in humans. Keep this and all drugs out of reach of children.** *In horses, there have been rare reports of swelling and irritation of the mouth, lips and tongue following administration of ZIMECTERIN Gold. These reactions have been transitory in nature. Do not use in other animal species as severe adverse reactions, including fatalities in dogs, may result.*

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<sup>1</sup>American Association of Equine Practitioners. Horse Health, Internal Parasites: Strategies for Effective Parasite Control. Available at: <https://aaep.org/horsehealth/internal-parasites-strategies-effective-parasite-control>. Accessed February 9, 2017.

<sup>2</sup>GASTROGARD product label.

<sup>3</sup>McClure S. AAEP Equine Gastric Ulcers: Special Care and Nutrition. Available at: <https://aaep.org/horsehealth/equine-gastric-ulcers-special-care-and-nutrition>. Accessed March 15, 2017.

<sup>4</sup>ULCERGARD product label.

<sup>5</sup>Based on Market Dynamics, Inc. AHS study data for Q12016 Moving Annual Total. Ranking represents cumulative dollar sales volume over the period.

# GASTROGARD®

(omeprazole) oral Paste for Equine Horses

## Oral Paste for Horses and Foals

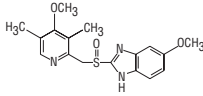
- NADA 141-123, Approved by FDA

## Caution

- Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

## Description

- Chemical name: 5-Methoxy-2-[[[4-methoxy-3,5-dimethyl-2-pyridinyl] methyl]sulfinyl]-1H-benzimidazole. Empirical formula: C<sub>17</sub>H<sub>19</sub>N<sub>3</sub>O<sub>3</sub>S. Molecular weight: 345.42. Structural formula:



## How Supplied

- GastroGard (omeprazole) Paste for horses contains 37% w/w omeprazole and is available in an adjustable-dose syringe. Each syringe contains 2.28 g of omeprazole. Syringes are calibrated according to body weight and are available in boxes of 7 units or 72 units.

## Storage Conditions

- Store at 68°F – 77°F (20-25°C). Excursions between 59°F – 86°F (15-30°C) are permitted.

## Indications

- 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 should be administered orally once-a-day for 4 weeks at the recommended dosage 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

- 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 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 500 lb (227 kg) body weight.

- To deliver GastroGard Paste at the treatment 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 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 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 ¼ 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 part of 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

- 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<sup>+</sup>, K<sup>+</sup> ATPase enzyme

which pumps hydrogen ions into the lumen of the stomach in exchange for potassium ions. Since omeprazole accumulates in the cell canaliculi and is irreversibly bound to the effect site, the plasma concentration at steady state is not directly related to the amount that is bound to the enzyme. The relationship between omeprazole action and plasma concentration is a function of the rate-limiting process of H<sup>+</sup>, K<sup>+</sup> ATPase activity/turnover. Once all of the enzyme becomes bound, acid secretion resumes only after new H<sup>+</sup>, K<sup>+</sup> ATPase is synthesized in the parietal cell (i.e., the rate of new enzyme synthesis exceeds the rate of inhibition).

- **Pharmacodynamics:** In a study of pharmacodynamic effects using horses with gastric canulae, 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 99%, 95% and 90% at 8, 16, and 24 hours, respectively.

- **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 (AUC<sub>0-∞</sub>). When comparing the individual bioavailability data (AUC<sub>0-∞</sub>, C<sub>max</sub>, and T<sub>max</sub> measurements) across the study days, there was great inter- and intrasubject 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 AUC<sub>0-∞</sub> 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

- **Dose Confirmation:** GastroGard (omeprazole) Paste, administered to provide omeprazole at 1.8 mg/lb (4 mg/kg) daily for 28 days, effectively healed or reduced the severity of gastric ulcers in 92% of omeprazole-treated horses. In comparison, 32% of controls exhibited healed or less severe ulcers. Horses enrolled in this study were healthy animals confirmed to have gastric ulcers by gastroscopy. 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.

- **Clinical Field Trials:** GastroGard Paste administered at 1.8 mg/lb (4 mg/kg) daily for 28 days healed or reduced the severity of gastric ulcers in 99% of omeprazole-treated horses. In comparison, 32.4% of control horses had healed ulcers or ulcers which were reduced in severity. These trials included horses of various breeds and under different management conditions, and included horses in race or show training, pleasure horses, and foals as young as one month. Horses enrolled in the efficacy trials were healthy animals confirmed to have gastric ulcers by gastroscopy. In these field trials, horses readily accepted GastroGard Paste. There were no drug related adverse reactions. In the clinical trials, GastroGard Paste was used concomitantly with other therapies, which included: anthelmintics, antibiotics, non-steroidal and steroidal anti-inflammatory agents, diuretics, tranquilizers and vaccines.

- **Diagnostic and Management Considerations:** The following clinical signs may be associated with gastric ulceration in adult horses: inappetence or decreased appetite, recurrent colic, intermittent loose stools or chronic diarrhea, poor hair coat, poor body condition, or poor performance. Clinical signs in foals may include: bruxism (grinding of teeth), excessive salivation, colic, cranial abdominal tenderness, anorexia, diarrhea, sternal recumbency or weakness. A more accurate diagnosis of gastric ulceration in horses and foals may be made if ulcers are visualized directly by endoscopic examination of the gastric mucosa. 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) for control of gastric ulcers following treatment. 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 effects 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 foal 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 66 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.

## Reproductive 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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