

elevel⁺

Omeprazole Paste for Horses



ACTIVE CONSTITUENT

Omeprazole 370 mg/g

ACTIONS

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 cells 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 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⁺, K⁺, ATPase activity/turnover. Once all the enzyme becomes bound, acid secretion resumes only after new H⁺, K⁺, ATPase is synthesised in the parietal cell (i.e., the rate of new enzyme synthesis exceeds the rate of inhibition).

INDICATIONS

elevel+® Omeprazole Paste for Horses is for the treatment and prevention of recurrence of gastric ulcers in horses and foals 4 weeks of age and older. For use by or under direction of a registered veterinarian.

RESTRAINTS

DO NOT USE in horses that may be used for human consumption.

PRECAUTIONS

Use with caution in pregnant or lactating mares as the safety of this product has not been determined in those classes of animals. The safety of omeprazole for longer than 91 days treatment has not been determined.

DOSAGE & ADMINISTRATION

Use product within 28 days after opening and discard unused portion.

This product is recommended for use in horses and foals 4 weeks of age or older.

The paste is for use orally at the recommended dose rate for either treatment or prevention.

A single 33 g syringe will treat one horse weighing 600 kg for 5 days at the treatment rate of 4 mg/kg.

TREATMENT DOSE: 4 mg/kg. Adult horse (600 kg) give 6 mL daily for 28 days (1 mL per 100 kg).

PREVENTION DOSE: 1 mg/kg. Adult horse (600 kg) give 1.5 mL daily for 28 days (0.25 mL per 100 kg).

Please refer to dosage table below for actual volume to be administered.

DOSAGE GUIDE

Horse Bodyweight (kg)	Treatment dose volume (mL)	Prevention dose volume (mL) *‡
100	1.0	0.3
200	2.0	0.5
300	3.0	0.8
350	3.5	0.9
400	4.0	1.0
450	4.5	1.2
500	5.0	1.3
550	5.5	1.4
600	6.0	1.5
650	6.5	1.7

* A disposable syringe may be used to measure small volumes below 2 mL more accurately.

‡ Gastric ulcers may recur following completion of the initial treatment unless treatment is continued at the preventative dose rate.

To set the syringe plunger, unlock the plastic adjuster by rotating at 45 degrees. Slide the plastic plunger along the plunger shaft so that the side nearest the barrel is at the appropriate notch. Rotate the plastic adjuster 45 degrees to lock it in place and ensure it is locked. To administer set dial-a-dose syringe to required volume. Make sure the horse's mouth contains no feed. Remove the plastic cap from the tip of the syringe and insert the syringe into the horse's mouth in the gap between the front and back teeth. Deposit the paste towards the back of the tongue by depressing the plunger quickly as far as it will go.

The product is a sticky, free flowing paste so ensure that it is applied onto the internal parts of the mouth, not just dropped into the oral cavity. Immediately raise the horse's head for a few seconds after dosing to ensure the full dose has been swallowed. 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.

ADDITIONAL USAGE GUIDANCE

elevet+® Omeprazole Paste for Horses can be used concomitantly with other medication including anthelmintics, antibiotics, vaccines, nonsteroidal anti-inflammatory drugs and other commonly administered veterinary preparations.

In previous efficacy trials, when the drug was administered at 4 mg omeprazole/kg bodyweight daily for 28 days and 2 mg omeprazole/kg bodyweight daily for additional 30 days, no adverse reactions were observed.

WITHHOLDING PERIODS

MEAT WITHHOLDING PERIOD (HORSES): DO NOT USE in horses that may be used for human consumption.

SAFETY DIRECTIONS

May irritate the eyes and skin. Avoid contact with eyes and skin. Wash hands after use.

SAFETY DATA SHEET

For Safety Data Sheet see www.avet.health

FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre on 13 11 26 (Australia). If product in eye, wash it out immediately with water.

DISPOSAL

Dispose of syringe by wrapping with paper and putting in garbage.

STORAGE

Store below 25 °C (air conditioning) in a dry place.

PRESENTATION

Pack of 6 x 33 g syringes

Bucket of 50 x 33 g syringes

POISONS SCHEDULE

S4

REGISTRATION NUMBERS

APVMA Approval Number: 90371