Boehringer Ingelheim

Approved by FDA under NADA # 141-214

Zimecterin® Gold

(ivermectin 1.55% / praziquantel 7.75%) Paste

For oral use in horses only

INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. ZIMECTERIN® GOLD (ivermectin/praziquantel) Paste provides effective treatment and control of the following parasites in horses. **Tapeworms** – Anoplocephala perfoliata, **Large Strongyles** (adults) – Strongylus vulgaris (also early forms in blood vessels), S. edentatus (also tissue stages), S. equinus, Triodontophorus spp. including T. brevicauda and T. serratus and Craterostomum acuticaudatum; **Small Strongyles** (adults, including those resistant to some benzimidazole class compounds) – Coronocyclus spp. including C. coronatus, C. labiatus and C. labratus, Cyathostomum spp. including C. catinatum and C. pateratum, Cylicocyclus spp. including C. insigne, C. leptostomum, C. nassatus, and C. brevicapsulatus, Cylicodontophorus spp., Cylicostephanus spp., including C. calicatus, C. goldi, C. longibursatus and C. minutus, and Petrovinema poculatum; **Small Strongyles** – Fourth-stage larvae; **Pinworms** (adults and fourth-stage larvae) – Oxyuris equi; **Ascarids** (adults and third- and fourth-stage larvae) – Parascaris equorum; **Hairworms** (adults) – Trichostrongylus axei; **Large-mouth Stomach Worms** (adults) – Habronema muscae; **Bots** (oral and gastric stages) – Gasterophilus spp. including G. intestinalis and G. nasalis; **Lungworms** (adults and fourth-stage larvae) – Dictyocaulus arnfieldi; **Intestinal Threadworms** (adults) – Strongyloides westeri; **Summer Sores** caused by Habronema and Draschia spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, Onchocerca sp.

DOSAGE: This syringe contains sufficient paste to treat one 1250 lb horse at the recommended dose rate of 91 mcg ivermectin per lb (200 mcg/kg) body weight and 454 mcg praziquantel per lb (1 mg/kg) body weight. Each weight marking on the syringe plunger delivers enough paste to treat 250 lb body weight.

Do not underdose. Ensure each animal receives a complete dose based on a current body weight.

Underdosing may result in ineffective treatment, and encourage the development of parasite resistance.

PARASITE CONTROL PROGRAM: All horses should be included in a regular parasite control program with particular attention being paid to mares, foals and yearlings. Foals should be treated initially at 2 months of age, and routine treatment repeated as appropriate. Consult your veterinarian for a control program to meet your specific needs.

ZIMECTERIN® GOLD Paste effectively controls gastrointestinal cestodes, nematodes and bots of horses. Regular treatment will reduce the chances of verminous arteritis caused by Strongylus vulgaris.

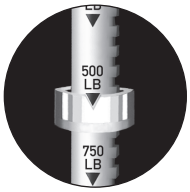
PRODUCT ADVANTAGES: Broad-spectrum Control — ZIMECTERIN® GOLD Paste kills important internal parasites, including tapeworms, bots and the arterial stages of S. vulgaris, with a single dose.

ZIMECTERIN® GOLD Paste is a potent antiparasitic agent that is neither a benzimidazole nor an organophosphate.

ANIMAL SAFETY: ZIMECTERIN® GOLD Paste may be used in horses two months of age or older. ZIMECTERIN® GOLD Paste has not been tested in foals younger than two months of age, mares at or near the time of breeding, pregnant or lactating mares, and breeding stallions. ZIMECTERIN® GOLD Paste, when tested at 1, 3 and 5-times the maximum recommended dose every two weeks in 5-month old foals, and at 10-times the maximum recommended dose in a separate study, did not elicit any adverse clinical signs of toxicity. In a foal safety study in younger animals, ZIMECTERIN® GOLD Paste was found safe at up to 3-times the maximum recommended dose in 2-month old foals.

STORAGE: Store up to 86°F (30°C). Transient exposure to temperatures up to 104°F (40°C) is permitted.

ADMINISTRATION



1) While holding plunger, turn the knurled ring on the plunger ¼ turn to the left and slide it so the side nearest the barrel is at the prescribed weight marking, aligning the arrow on the plunger with the notch on the ring, as shown in the pictogram.

2) Lock the ring in place by making ¼ turn to the right. Ensure it is locked (it should no longer slide).

3) Make sure that the horse's mouth contains no feed.

4) Remove the cover from the tip of the syringe.

5) Insert the syringe tip into the horse's mouth at the space between the teeth.

6) Depress the plunger as far as it will go, depositing paste on the back of the tongue.

7) Immediately raise the horse's head for a few seconds after dosing.

WARNING: Do not use in horses intended for human consumption. Not for use in humans. Keep this and all drugs out of reach of children. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes. The Safety Data Sheet (SDS) contains more detailed occupational safety information. To report adverse reactions in users, to obtain more information, or to obtain a SDS, contact Boehringer Ingelheim Animal Health USA Inc. at 1-888-637-4251.

PRECAUTIONS: ZIMECTERIN® GOLD (ivermectin/praziquantel) Paste has been formulated specifically for use in horses **only**. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

OTHER WARNINGS: Parasite resistance may develop to any dewormer, and has been reported for most classes of dewormers. Treatment with a dewormer used in conjunction with parasite management practices appropriate to the geographic area and the animal(s) to be treated may slow the development of parasite resistance. Fecal examinations or other diagnostic tests and parasite management history should be used to determine if the product is appropriate for the herd, prior to the use of any dewormer. Following the use of any dewormer, effectiveness of treatment should be monitored (for example, with the use of a fecal egg count reduction test or another appropriate method). A decrease in a drug's effectiveness over time as calculated by fecal egg count reduction tests may indicate the development of resistance to the dewormer administered. Your parasite management plan should be adjusted accordingly based on regular monitoring.

Post-Approval Experience: Although not all adverse reactions are reported, the following reactions are based on voluntary post-approval drug experience reporting. 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.

Environmental Safety: Ivermectin and excreted ivermectin residues may adversely affect aquatic organisms.

Do not contaminate ground or surface water. Dispose of the syringe in an approved landfill or by incineration.

Information For Horse Owners: Swelling and itching reactions after treatment with ivermectin have occurred in horses carrying heavy infections of neck threadworm (Onchocerca sp.) microfilariae. These reactions were most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable. Consult your veterinarian should any such reactions occur. Healing of summer sores involving extensive tissue changes may require other appropriate therapy in conjunction with treatment with ZIMECTERIN® GOLD Paste. Reinfection, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.

Marketed by: Boehringer Ingelheim Animal Health USA Inc.

Duluth, GA 30096

Made in Brazil

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