CAUTION: Federal law (U.S.A.) restricts this drug to use by or on the order of a licensed veterinarian.

Topical Solution for the treatment and control of hookworm, roundworm and tapeworm infections in cats and kittens that are at least 8 weeks of age and weigh at least 2.2 lbs (1 kg).

DESCRIPTION:

PROFENDER Topical Solution is indicated for the treatment and control of hookworm infections caused by Ancylostoma tubaeforme (adults, immature adults, and fourth stage larvae), roundworm infections caused by Toxocara cati (adults and fourth stage larvae), and tapeworm infections caused by Dipylidium caninum (adults) and Taenia taeniaeformis (adults) in cats.

INDICATIONS:

Emodepside, a semi-synthetic molecule, is a cyclic depsipeptide. The chemical name is Cyclo-[D-2-hydroxypropanoyl-N-methyl-L-leucyl-3-[4-(4-morpholinyl)phenyl]-D-2-hydroxypropanoyl-N-methyl-L-leucyl]-D-2-hydroxypropanoyl-N-methyl-L-leucyl].

Praziquantel is an isoquinoline cestocide. The chemical name is 2-Cyclohexylcarbonyl-1,2,3,6,7,11b-hexahydro-4H-pyrazine-2,1-a-isoquinoline-4-one.

PRECAUTIONS:

Safe use of this product has not been evaluated in cats less than 8 weeks of age or weighing less than 2.2 lbs (1 kg). In cats used for breeding or in lactating queens. The effectiveness of this product when used before bathing has not been evaluated. Use with caution in sick or debilitated cats. Oral ingestion or exposure should be avoided. Use with caution in heartworm positive cats. The cats enrolled in the field study were heartworm antigen and antibody negative prior to entering the study. The laboratory study, cats artificially infected with adult heartworms and treated with PROFENDER Topical Solution had fewer worms recovered than the placebo control group. (See ANIMAL SAFETY.)

ADVERSE REACTIONS:

Field study: In a controlled, double-masked field safety study, owners administered PROFENDER Topical Solution to 606 cats. Adverse reactions reported by the cat owners included licking/excessive grooming in 18 cats (3.0%), scratching treatment site in 15 cats (2.5%), salivation in 10 cats (1.7%), lethargy in 10 cats (1.7%), alopecia in 8 cats (1.3%), agitation/irritability in 7 cats (1.2%), vomiting in 6 cats (1.0%), diarrhea in 5 cats (0.8%), diarrhea with mucus in 3 cats (0.5%), diarrhea with blood in 2 cats (0.3%), salivation in 1 cat (0.2%) and shaking/fremitus in 1 cat (0.2%). All adverse reactions were self-limiting.

Laboratory effectiveness studies: One cat died 10 days after receiving PROFENDER Topical Solution. The necropsy showed chronic active cholangiohepatitis. While the use of the drug did not appear to be the direct cause of death, treatment with the drug cannot be ruled out as a contributing factor. (See PRECAUTIONS.)

One cat treated with a single topical dose to young adult cats. The cats exhibited salivation, vomiting, tremors, abnormalities of behavior, hypoglycemia, and death.

ANIMAL SAFETY:

In a field study, PROFENDER Topical Solution was used in cats receiving other frequently used products including: analgesics, anti-fungals, non-steroidal anti-inflammatories, anthelmintics, antibiotics, analgesics, anti-fungals, steroids, vaccines, vitamins, and other miscellaneous products. None of the adverse reactions noted were attributed to the use of the product. The reactions noted were self-limiting.

Storage Information:

Store at or below 77°F (25°C). Protect from freezing.

How Supplied:

Code Number Applications per Package
82482521 20 – 0.35 ml tubes (5 blisters of 4 tubes)
82482526 40 – 0.35 ml tubes (10 blisters of 4 tubes)
82482572 20 – 0.7 ml tubes (5 blisters of 4 tubes)
82482534 40 – 0.7 ml tubes (10 blisters of 4 tubes)
82482580 20 – 1.12 ml tubes (5 blisters of 4 tubes)
82482602 40 – 1.12 ml tubes (10 blisters of 4 tubes)

PROFENDER Topical Solution may be irritating to skin and eyes. Reactions such as facial, tongue and hand swelling have been reported in humans in rare instances. Avoid contact with the application area while it is wet and wash hands thoroughly with soap and warm water after handling. People with known hypersensitivity to butylhydroxyanisole, emodepside or praziquantel should administer the product with caution. If the product accidental gets into eyes, wash thoroughly with water. Make it harmful if swallowed. In case of accidental ingestion or if skin or eye irritation occurs, call a poison control center or physician for treatment advice.

The Material Safety Data Sheet (MSDS) provides additional occupational safety information. For customer service or to obtain product information, including the MSDS, call 1-800-633-3796. For medical emergencies or to report an adverse reaction, call 1-800-422-9874.