

Emodepside/Praziquantel

(ee-moe-dep-side / pra-zi-kwon-tel)

Description:

Topical Antiparasitic

Other Names for this Medication: Profender®

Common Dosage Forms:

Veterinary: 1.98% emodepside/7.94% praziquantel topical solution in 0.35 mL, 0.7 mL, & 1.12 mL tubes. Human: None.

This information sheet does not contain all available information for this medication and has not been reviewed by FDA Center for Veterinary Medicine. This sheet can help answer commonly asked questions but is not a substitute for medical advice. If you have other questions or need more information about this medication, contact your veterinarian or pharmacist.

Key Information

- Topical (spot-on) for treatment and control of hookworms, roundworms, and tapeworms in cats. Applied once. If your animal becomes infected again, it may be treated again in 30 days.
- Well tolerated.
- Do not apply to broken skin or if hair coat is wet.
- Do not allow cats to lick the application site for one hour. In cats, contact with the mouth or eyes can cause salivation and vomiting; treatment at the base of the head reduces the chance for ingestion while grooming.
- In households with multiple pets, keep animals separated for one hour to prevent licking of the application site.
- Not for human use. Keep out of reach of children. To prevent accidental ingestion of the product, children should not come in contact with the application site for 24 hours.
- Women who are pregnant or may become pregnant should avoid direct contact with, or wear disposable gloves when applying this product.

How is this medication useful?

Emodepside with praziquantel topical solution (Profender®) is approved by the FDA (U.S. Food & Drug Administration) 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 lb. (1 kg). You and your veterinarian can discuss why this drug is the most appropriate choice.

What should I tell my veterinarian to see if this medication can be safely given?

Many things might affect how well this drug will work in your animal. Be sure to discuss the following with your veterinarian so together you can make the best treatment decisions.

- Other drugs can interact with this medication, so be sure to tell your veterinarian and pharmacist what medications (including vitamins, supplements, or herbal therapies) you give your animal, including the amount and time you give each.
- Tell your veterinarian about any conditions or diseases your animal may have now or has had in the past.
- If your animal has been treated for the same disease or condition in the past, tell your veterinarian about the treatment and how well it did or didn't work.
- If your animal is pregnant or nursing, talk to your veterinarian about the risks of using this drug.
- Tell your veterinarian and pharmacist about any medication side effects (including allergic reactions, lack of appetite, diarrhea, itching,

hair loss) your animal has developed in the past.

How long until I will know if this medication is working, and how long will the effects of this medication last?

This medication should help your animal feel better within 1 to 2 days. Your animal's clinical signs should improve after that time. The effects of this medication are short-lived, meaning they will stop working within 24 hours; however, for this medication to protect your animal against intestinal parasites, it must be given monthly.

When should this medication not be used or be used very carefully?

No drug is 100% safe in all patients, but your veterinarian will discuss with you any specific concerns about using this drug in your animal.

This drug combination **SHOULD NOT** be used in cats:

• That are allergic to either emodepside or praziquantel.

This drug combination should be used WITH CAUTION in cats:

- Less than 8 weeks of age or weighing less than 2.2 lb. (1 kg) as safe use of this product has not yet been studied.
- Used for breeding, during pregnancy, or in lactating queens as safe use of this product has not yet been studied.
- That are sick or weak.
- That have tested positive for heartworm infection.

If your animal has any of these conditions, talk to your veterinarian about the potential risks versus benefits.

What are the side effects of this medication? Most

cats tolerate this medication very well.

Side effects (reported in less than 5% of cats treated) that are usually not serious, include:

- Licking or excessive grooming.
- Scratching at the treatment site.
- Excessive salivation (drooling).
- Lack of energy.
- Loss of fur.
- Agitation (anxious, nervous, pacing, unable to settle).
- Vomiting.

You don't have to be overly concerned if you see any of these signs unless they are severe, are persistent, or worsen. Contact your veterinarian if this happens.

If my animal gets too much of this medication (an overdose), what should I do?

If you witness or suspect an overdose or if the drug is eaten by an animal, contact your veterinarian or an animal poison control center for further advice. Animal poison control centers that are open 24 hours a day include: **ASPCA Animal Poison Control Center** (888-4264435) and **Pet Poison HELPLINE** (855-764-7661); a consultation fee is charged for these services.

How should this medication be given?

For this medication to work, give it exactly as your veterinarian has prescribed. It's a good idea to always check the prescription label to be sure you are giving the drug correctly.

- A single treatment is usually effective. If reinfection occurs, the product can be applied again in 30 days.
- Do not apply to broken skin or wet fur.
- Remove one unit dose tube from the package.
- While holding the tube in an upright position, remove the cap from the tube.

Turn the cap over and place the other end of cap onto the tip of the tube.

Twist the cap to break the seal, then remove cap from the tube.

Part the hair on the back of the cat's neck at the base of the head, until the skin is visible.

Place the tip of the tube on the skin and squeeze the entire contents directly onto the skin. Lift tube away from the skin before releasing pressure on the tube.

- Do not get this product in the cat's mouth or eyes or allow the cat to lick the application site for one hour. Oral exposure can cause salivation and vomiting. Treatment at the base of the head will minimize the chance for ingestion while grooming. In households with multiple pets, keep animals separated for an hour to prevent mutual licking of the application site.
- Hair may appear stiff, damp, or a slight powdery residue may be observed at the treatment site. These effects are temporary and do
 not affect the safety or effectiveness of the product.
- The effectiveness of this product when used before bathing has not been evaluated, so don't bathe your cat or wash the treated area for a few days after treatment.

(Adapted from label; Profender®)

What should I do if I miss giving a dose of this medication?

If you miss a dose, give it when you remember and then wait the amount of time between doses recommended by your veterinarian before giving another dose. Do not double-up or give extra doses.

How should I store this medication?

- Store at or below 77°F (25°C, room temperature).
- Protect from freezing.
- Keep away from children and other animals.

Can handling this medication be hazardous to me, my family, or other animals?

- To prevent accidental ingestion of the product, children should not come in contact with the application site for 24 hours while the product is being absorbed. Women who are pregnant women or women who may become pregnant should avoid direct contact with or wear disposable gloves when applying, this product.
- The 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. Wash hands thoroughly with soap and warm water after handling the product. People with known allergies to butylhydroxyanisole, emodepside, or praziquantel should handle the

product with caution. If the product accidentally gets into eyes, flush thoroughly with water. May be harmful if swallowed. In case of human accidental ingestion or if skin or eye irritation occurs, call a poison control center or physician.

How should I dispose of this medication if I don't use it all?

- Do not flush this medication down the toilet or wash it down the sink. If a community drug "take-back" program is available, use this option. If there is no take-back program, mix the drug with coffee grounds or cat litter (to make it undesirable to children and animals and unrecognizable to people who might go through your trash), place the mixture in a sealable plastic bag to keep it from leaking out, and throw the bag out with the regular trash.
- Do not save leftover medication for future use or give it to others to use.

What other information is important for this medication?

Use of this drug may not be allowed in certain animal competitions. Check rules and regulations before entering your animal in a competition while this medication is being administered.

If you have any other questions about this medication, contact your veterinarian or pharmacist.