

Barrier® for Dogs and Cats (imidacloprid + moxidectin)

Topical Solution

BRIEF SUMMARY: Before using Barrier for Dogs (imidacloprid + moxidectin) or Barrier for Cats (imidacloprid + moxidectin), please consult the product insert, a summary of which follows:

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

Barrier® for Dogs:

WARNING

- **DO NOT ADMINISTER THIS PRODUCT ORALLY.**
- **For the first 30 minutes after application ensure that dogs cannot lick the product from application sites on themselves or other treated animals.**
- **Children should not come in contact with the application sites for two (2) hours after application.**

(See Contraindications, Warnings, Human Warnings, and Adverse Reactions for more information.)

INDICATIONS:

Barrier for Dogs is indicated for the prevention of heartworm disease caused by *Dirofilaria immitis* and the treatment of *Dirofilaria immitis* circulating microfilariae in heartworm-positive dogs. Barrier for Dogs kills adult fleas and is indicated for the treatment of flea infestations (*Ctenocephalides felis*). Barrier for Dogs is indicated for the treatment and control of *sarcoptic mange* caused by *Sarcoptes scabiei var. canis*. Barrier for Dogs is also indicated for the treatment and control of the following intestinal parasites species: Hookworms (*Ancylostoma caninum*) (*Uncinaria stenocephala*), Roundworms (*Toxocara canis*) (*Toxascaris leonina*) and Whipworms (*Trichuris vulpis*).

Barrier for Cats is indicated for the prevention of heartworm disease caused by *Dirofilaria immitis*. Barrier for Cats kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment of flea infestations. Barrier for Cats is also indicated for the treatment and control of ear mite (*Otodectes cynotis*) infestations and the intestinal parasites species Hookworm (*Ancylostoma tubaeforme*) and Roundworm (*Toxocara cati*). **Ferrets:** Barrier for Cats is indicated for the prevention of heartworm disease in ferrets caused by *Dirofilaria immitis*. Barrier for Cats kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment of flea infestations in ferrets.

CONTRAINDICATIONS: Do not administer this product orally. (See WARNINGS). Do not use the Dog product (containing 2.5% moxidectin) on Cats.

WARNINGS:

Barrier for Dogs: For the first 30 minutes after application: Ensure that dogs cannot lick the product from application sites on themselves or other treated dogs, and separate treated dogs from one another and from other pets to reduce the risk of accidental ingestion. Ingestion of this product by dogs may cause serious adverse reactions including depression, salivation, dilated pupils, incoordination, panting, and generalized muscle tremors. In avermectin sensitive dogs^a, the signs may be more severe and may include coma and death^b.

^a Some dogs are more sensitive to avermectins due to a mutation in the MDR1 gene. Dogs with this mutation may develop signs of severe avermectin toxicity if they ingest this product. The most common breeds associated with this mutation include Collies and Collie crosses.

^b Although there is no specific antagonist for avermectin toxicity, even severely affected dogs have completely recovered from avermectin toxicity with intensive veterinary supportive care.

Barrier for Cats: Do not use on sick, debilitated, or underweight cats. Do not use on cats less than 9 weeks of age or less than 2 lbs. body weight. Do not use on sick or debilitated ferrets.

HUMAN WARNINGS: Not for human use. Keep out of the reach of

children. Dogs: Children should not come in contact with the application sites for two (2) hours after application. Cats: Children should not come in contact with the application site for 30 minutes after application.

Causes eye irritation. Harmful if swallowed. Do not get in eyes or on clothing. Avoid contact with skin. **Wash hands thoroughly with soap and warm water after handling.** If contact with eyes occurs, hold eyelids open and flush with copious amounts of water for 15 minutes. If eye irritation develops or persists, contact a physician. If swallowed, call poison control center or physician immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or physician. People with known hypersensitivity to benzyl alcohol, imidacloprid, or moxidectin should administer the product with caution. In case of allergic reaction, contact a physician. If contact with skin or clothing occurs, take off contaminated clothing. Wash skin immediately with plenty of soap and water. Call a poison control center or physician for treatment advice. The Safety Data Sheet (SDS) provides additional occupational safety information. For a copy of the Safety Data Sheet (SDS), to report adverse reactions, or consumer questions call Aurora Pharmaceutical at 1-888-215-1256.

PRECAUTIONS: Do not dispense dose applicator tubes without complete safety and administration information. Use with caution in sick, debilitated or underweight animals. The safety of Barrier for Dogs has not been established in breeding, pregnant, or lactating dogs. The safe use of Barrier for Dogs has not been established in puppies and dogs less than 7 weeks of age or less than 3 lbs. body weight. Barrier for Dogs has not been evaluated in heartworm-positive dogs with Class 4 heartworm disease.

Cats may experience hypersalivation, tremors, vomiting and decreased appetite if Barrier for Cats is inadvertently administered orally or through grooming/licking of the application site. The safety of Barrier for Cats has not been established in breeding, pregnant, or lactating cats. The effectiveness of Barrier for Cats against heartworm infections (*D. immitis*) after bathing has not been evaluated in cats. Use of this product in geriatric cats with subclinical conditions has not been adequately studied. Ferrets: The safety of Barrier for Cats has not been established in breeding, pregnant, and lactating ferrets. Treatment of ferrets weighing less than 2.0 lbs. (0.9kg) should be based on a risk-benefit assessment. The effectiveness of Barrier for Cats in ferrets weighing over 4.4 lbs. (2.0 kg) has not been established.

ADVERSE REACTIONS: Heartworm Negative Dogs: The most common adverse reactions observed during field studies were pruritus, residue, medicinal odor, lethargy, inappetence and hyperactivity.

Heartworm Positive Dogs: The most common adverse reactions observed during field studies were cough, lethargy, vomiting, diarrhea (including hemorrhagic), and inappetence. **Cats:** The most common adverse reactions observed during field studies were lethargy, behavioral changes, discomfort, hypersalivation, polydipsia and coughing and gagging. **Ferrets:** The most common adverse reactions observed during field studies were pruritus/scratching, scabbing, redness, wounds and inflammation at the treatment site; lethargy; and chemical odor.

For a copy of the Safety Data Sheet (SDS) or to report adverse reactions call Aurora Pharmaceutical, Inc. at 1-888-215-1256 or www.aurorapharmaceutical.com.

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