

Prescription Label

Patient Name:

Species:

Drug Name & Strength:

Directions (amount to give how often & for how long):

Prescribing Veterinarian's Name & Contact Information:

Refills:

[Content to be provided by prescribing veterinarian]

Selamectin

(*sell-a-mek-tin*)

Description:

Agent for Prevention of Heartworm Disease; Prevention & Control of Flea Infestations; Treatment & Control of Ear Mites; Treatment & Control of Sarcoptic Mange (Dogs Only); Control of *Dermacentor variabilis* Tick Infestations (Dogs Only); Treatment & Control of Roundworm & Intestinal Hookworm Infections (Cats Only).

Other Names for this Medication:

Revolution[®], Paradyne[®]

Common Dosage Forms:

60 mg/mL & 120 mg/mL liquid for topical application. Available in different sizes based on animal's body weight. Dogs: less than 5 lbs (15 mg, 0.25 mL), 5.1 - 10 lbs (30 mg, 0.25 mL), 10.1-20 lbs (60 mg, 0.5 mL), 20.1-40 lbs (120 mg, 1 mL), 40.1-85 lbs (240 mg, 2 mL), & 85.1-130 lbs (360 mg, 3 mL). Cats: less than 5 lbs (15 mg, 0.25 mL), 5.1-15 lbs (45 mg, 0.75 mL), & 15.1-22 lbs (60 mg, 1 mL). **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

- Labeled for monthly use in dogs and puppies 6 weeks of age and older and cats and kittens 8 weeks of age and older.
- Dogs: Kills adult fleas and prevents flea eggs from hatching for one month. Prevents heartworm disease, treats ear mites, treats sarcoptic mange, and controls *Dermacentor variabilis* tick infestations.
- Cats: Kills adult fleas and prevents flea eggs from hatching for one month. Prevents heartworm disease, treats ear mites, and treats hookworms and roundworms
- Not for use in dogs and cats infected with adult heartworms.
- When used as directed on the label, side effects are not likely.

- Dispose of empty containers in the regular trash; do not pour unused product down the drain.

How is this medication useful?

Selamectin is used in dogs and cats to prevent heartworm disease, for treatment and control of flea and ear mite infestations. In dogs, it is also labeled for control of tick infestations due to *Dermacentor variabilis* and treatment and control of sarcoptic mange. In cats, selamectin is also labeled for treatment and control of roundworm and intestinal hookworm infections. The FDA (U.S. Food & Drug Administration) has approved this drug for use in dogs and puppies 6 weeks of age and older and cats and kittens 8 weeks of age or older. The FDA does allow veterinarians to prescribe and use products containing this drug in different species or for other conditions in certain situations. 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 drug, 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?

Fleas will begin to die within 4 to 8 hours; ticks can take up to 5 days to kill the majority of ticks on your dog. Your animal's clinical signs should begin to improve after that time. The effects of this medication are long-lived, meaning they may last for multiple (ie, 4 to 6) weeks, although they may be prolonged if your animal has decreased kidney and/or liver function. For this medication to protect your animal against infection by heartworms and 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 **SHOULD NOT** be used in animals that are:

- Allergic to selamectin or other avermectin drugs (eg, ivermectin)
- Less than 6 weeks old for dogs or less than 8 weeks old for cats
- Sick, debilitated, or underweight

This drug should be used **WITH CAUTION** in animals that:

- Are pregnant or nursing.
- Are receiving certain types of medications
- Are already receiving another flea or other parasite preventative
- Have not been tested 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?

When used as directed on the label, cats and dogs typically tolerate this drug well.

Side effects (rare) that usually are not serious include:

- Irritation and/or hair loss at the site of application.

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

Side effects that may be serious or indicate a serious problem include:

All are very rare, but may indicate an overdose or toxicity (especially in dogs with the *MDR1* genetic mutation most commonly found in “white feet” breeds: collies, Australian shepherds, Shetland sheepdogs [Shelties], long-haired whippets):

- Depression, lack of energy, or weakness.
- Stumbling or collapse.
- Seizures or coma.
- Dilated (big) pupils.
- Excessive drooling.

If you see any of these signs, contact your veterinarian immediately.

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

If you witness or suspect an overdose, contact your veterinarian or an animal poison control center immediately for further advice. Animal poison control centers that are open 24 hours a day include: **Pet Poison HELPLINE** (855-764-7661) and **ASPCA Animal Poison Control Center** (888-426-4435); 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 and package information to be sure you are giving the drug correctly.

- Make sure your animal is dry before applying this product.
- Using the appropriate sized tube for your animal's weight: Remove one applicator from child-resistant package. Hold applicator upright, pointed away from face. Push the cap down firmly until you hear a click. Remove the cap and check to make sure the seal has been broken.
- Position the dispensing tip on the animal's back, between the shoulder blades. Use the dispensing tip of the tube to part the animal's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube. Squeeze 3-4 times in one spot until empty.
- Avoid contact with treated area until dry.
- This medication can be administered for various lengths of time, so be sure you understand how long the veterinarian wants you to continue giving it. You may need to get refills before the therapy will be complete.

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

- If you miss a dose, apply 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.
- When using this product for heartworm prevention: If more than 8 weeks have passed without giving this medication, start giving the drug as soon as you remember. After that, continuing giving the medication monthly, but make sure to have your animal tested for heartworm infection 6 months later, as your dog may have become infected during the time the medication was not given.

How should I store this medication?

- Store this medication in the original package or an approved dosage reminder container (ie, pill minder) at a temperature less than 86°F (30°C).
- Keep product away from heat, sparks, open flames, or other sources of ignition.
- If your veterinarian or pharmacist has made (compounded) a special formulation for your animal, follow the storage recommendations and expiration date for the product.
- Keep away from children and other animals.

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

- The Revolution® product label states:

NOT FOR HUMAN USE. KEEP OUT OF REACH OF CHILDREN.

In humans, Revolution® may be irritating to skin and eyes. Reactions such as hives, itching and skin redness have been reported in humans in rare instances. Individuals with known hypersensitivity to Revolution® should use the product with caution or consult a health care professional. Revolution contains isopropyl alcohol and the preservative butylated hydroxytoluene (BHT). Wash hands after use and wash off any product in contact with the skin immediately with soap and water. If contact with eyes occurs, then flush eyes copiously with water. In case of ingestion by a human, contact a physician immediately.

- Wearing disposable gloves is not mandatory (not mentioned on label), but can be considered when applying this medication.
- Wash your hands after handling any medication.

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

- If any medication remains, call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain as this product can be toxic to fish and wildlife. Recommend putting the empty container in a sealed plastic bag before placing in trash or offer for recycling if available.
- Do not save leftover medication for future use or give it to others to use.

What other information is important for this medication?

- Do not reapply for thirty (30) days unless your veterinarian specifically instructs you to do so.
- When used on dogs, this product is effective 2 hours after application even after bathing, water immersion, or exposure to sunlight.
- This product does not kill/control all species of ticks. Talk with your veterinarian about whether additional tick control products are required. Do not apply any additional products without discussing with your veterinarian first.
- When used on cats, the application site must remain dry for 24 hours after application.
- Some animals may experience sticky fur, clumping of the fur, powder-like residue, or fur discoloration at the application site. These findings are temporary and do not affect your animal's safety or the effectiveness of the medicine.
- 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.

Special Instructions
