

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 and Sarolaner (Cats)

(sell-a-**mek**-tin; **sar**-oh-**lah**-ner)

Description: Agent for Prevention of Heartworm Disease; Treatment & Prevention of Flea Infestations; Treatment & Control of Tick Infestations; Treatment & Control of Ear Mite Infestations; Treatment & Control of Roundworm & Intestinal Hookworm Infections.

Other Names for this Medication: Revolution® Plus, Stronghold Plus

Common Dosage Forms: Veterinary: Selamectin 60 mg/mL and sarolaner 10 mg/mL liquid for topical application. Available in different sizes based on cat's body weight: 2.8-5.5 lbs (15 mg/2.5 mg; 0.25 mL); 5.6-11 lbs (30 mg/5 mg; 0.5 mL); 11.1-22 lbs (60 mg/10 mg; 1 mL). **Human:** None.

This information sheet does not contain all available information for this medication. It is to help answer commonly asked questions and help you give the medication safely and effectively to your animal. If you have other questions or need more information about this medication, contact your veterinarian or pharmacist.

Key Information

- ▶ Labeled for monthly use in cats and kittens 8 weeks of age or older and weighing 2.8 pounds or more.
- ▶ Kills adult fleas and prevents flea eggs from hatching for one month.
- ▶ Prevents heartworm disease, treats and controls mite and tick infestations, and treats and controls roundworm and intestinal hookworm infections for one month.
- ▶ Not for use in 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?

The combination product, selamectin and sarolaner, is used in cats to prevent heartworm infection and for treatment and control of flea, tick, and ear mite infestations. It is also approved for the treatment and control of roundworm and intestinal hookworm infections for one month. The FDA (U.S. Food & Drug Administration) has approved this drug for use in cats and kittens 8 weeks of age and older and weighing 2.8 pounds or more. 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 3 days to die and fall off your animal. 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 cats that are:

- ▶ Allergic to selamectin or other avermectin drugs (eg, ivermectin)
- ▶ Allergic to sarolaner
- ▶ Less than 8 weeks of age
- ▶ Weigh less than 2.8 pounds

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

- ▶ Are pregnant or nursing
- ▶ Are weak, old, or frail
- ▶ Are receiving certain medications
- ▶ Are receiving another flea or other parasite preventative
- ▶ Have not been tested for heartworm infection
- ▶ Have a history of neurologic disorders

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

What are the side effects of this medication?

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

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

- ▶ Hair loss and/or irritation at the site of application
- ▶ Itchiness
- ▶ Loss of appetite, vomiting, or diarrhea
- ▶ Red, irritated eyes (ie, conjunctivitis) or sneezing
- ▶ Low energy level

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:

- ▶ Depression, lack of energy, or weakness
- ▶ Stumbling or collapse
- ▶ Seizures, tremors
- ▶ 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 cat is dry before applying product.
- ▶ Do not apply to broken skin.
- ▶ Using the appropriately 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 the product is applied at skin level. Begin squeezing out the contents of the tube. Squeeze 3-4 times in one spot until empty. If 2 tubes are required due to your animal's weight, apply the contents of both applicators in the same spot.
- ▶ 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, continue giving the medication monthly. Talk with your veterinarian about having your animal tested for heartworm infection 6 months later, as your animal 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 at a temperature less than 86°F (30°C).
- ▶ Keep 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 product label states:
NOT FOR HUMAN USE. KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.
In humans, Revolution Plus may be irritating to skin and eyes. Revolution Plus and selamectin topical solution contains isopropyl alcohol and the preservative butylated hydroxytoluene (BHT). Reactions such as hives, itching and skin redness have been reported in humans in rare instances after accidental dermal contact with selamectin topical solution. Individuals with known hypersensitivity to selamectin topical solution should use caution or consult a health care professional before applying this product to a cat. 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; if wearing contact lenses, rinse the eyes first then move contact lenses and continue to rinse for 5-10 minutes and seek medical attention. 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.
- ▶ Empty containers can be disposed of in your regular household trash.
- ▶ Do not save leftover medication for future use or give it to others to use.

What other information is important for this medication?

- ▶ After applying, do not reapply for thirty (30) days unless your veterinarian specifically instructs you to do so. The Revolution® Plus product label indicates that the effectiveness of this combination product against heartworm infection after bathing has not been

evaluated. However, bathing your cat 24 hours after application does not reduce the effectiveness of selamectin (an ingredient found in this combination product) against heartworm infection.

- ▶ 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:
