

Client Information About



Selarid (pronounced "Sel-a-rid")

Generic name: selamectin ("sel-a-mec-tin")

This summary contains important information about Selarid. You should read this information before you start using Selarid on your dog or cat and review it each time your prescription is refilled. This sheet is provided only as a summary and does not take the place of instructions from your veterinarian. Talk to your veterinarian if you do not understand any of this information or if you want to know more about Selarid.

What is Selarid?

Selarid is a topical parasiticide that is applied to the skin of dogs six weeks of age and older and cats eight weeks of age and older to kill adult fleas and prevent flea eggs from hatching, prevent heartworm disease and protect your pet against other parasites (see below).

Why has my veterinarian prescribed Selarid?

Selarid has been prescribed by your veterinarian to treat, prevent and/or control the following parasites in your dog or cat:

Dog Parasites:

- Control and prevention of flea infestation (*Ctenocephalides felis*)
- Prevention of heartworm disease (*Dirofilaria immitis*)
- Treatment and control of ear mite infestation (*Otodectes cynotis*)
- Treatment and control of sarcoptic mange (*Sarcoptes scabiei*)
- Control of the American Dog Tick (*Dermacentor variabilis*)

Cat Parasites:

- Control and prevention of flea infestation (*Ctenocephalides felis*)
- Prevention of heartworm disease (*Dirofilaria immitis*)
- Treatment and control of ear mite infestation (*Otodectes cynotis*)
- Treatment and control of intestinal worms Roundworm (*Toxocara cati*) Hookworm (*Ancylostoma tubaeforme*)

What should I discuss with my veterinarian before Selarid is prescribed?

Your veterinarian is best suited to discuss and recommend appropriate medications for your dog or cat. It is important to discuss your pet's health history with your veterinarian so he/she can decide if Selarid is right for your animal.

Selarid should not be used in sick, debilitated or underweight animals.

Dogs should be tested for heartworm disease prior to giving Selarid. If your dog tests positive for adult heartworms, your veterinarian can recommend appropriate treatment.

Dogs infected with adult heartworms can safely be given Selarid.

If your cat is older than six months of age, your veterinarian may decide to test him/her for heartworm disease before prescribing Selarid. Cats infected with adult heartworms can be given Selarid to prevent further infections.

What dose of Selarid do I use on my dog or cat?

Your veterinarian will recommend the appropriate dose for your dog or cat based on your animal's body weight. You should not administer Selarid to dogs younger than 6 weeks of age or cats younger than 8 weeks of age. Selarid is available in eight separate dose strengths for dogs and cats of different weights.

What should I do if I do not give Selarid on time or miss a dose?

If you forget to apply a monthly dose of Selarid, immediately apply Selarid, resume monthly

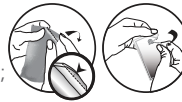
applications, and notify your veterinarian.

What if I administer more than the prescribed amount of Selarid to my dog or cat?

Contact your veterinarian if you administer more than the prescribed amount of Selarid.

How should Selarid be applied?

- Remove the applicator from the outer pouch using scissors or fold along diagonal line to expose nick; tear back at nick.
- Hold the applicator upright. Tap the narrow part of the applicator to ensure the contents remain within the main body of the applicator. Twist or snap back the tip.
- Part the hair on the back of the animal at the base of the neck, in front of the shoulder blades, until the skin is visible.
- Apply the tip of the Selarid applicator directly to the skin. Squeeze the applicator firmly 3–4 times in one spot until empty. Keep applicator compressed on the final squeeze to avoid drawing liquid back into applicator. Avoid contact between Selarid and your fingers.
- While keeping applicator squeezed, drag it away from liquid and lift up to remove.
- Ensure applicator is empty.



Do not massage Selarid into the skin.

Do not apply when the haircoat is wet.

Do not apply to broken skin – Selarid contains alcohol.

Stiff hair, clumping of hair, hair discoloration, or a slight powdery residue may be observed at the site in some animals. These effects are usually temporary and do not affect the safety or effectiveness of the product.

Can I give my pet a bath after applying Selarid?

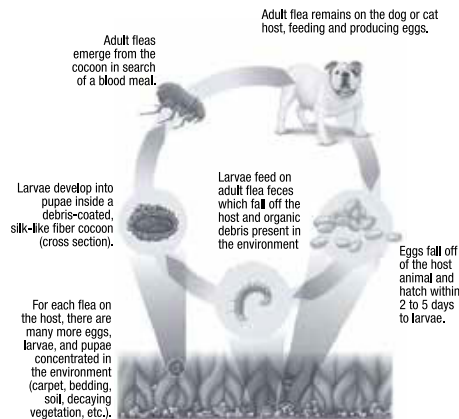
Yes. Bathing or shampooing the dog 2 or more hours after treatment will not reduce the effectiveness of Selarid against fleas or heartworm. Bathing or shampooing the cat 2 hours after treatment will not reduce the effectiveness of Selarid against fleas. Bathing or shampooing the cat 24 hours after treatment will not reduce the effectiveness of Selarid against heartworm.

When can I play with my pet following treatment with Selarid?

You should avoid contact with application site when wet. You may hold or play with your pet any time after the area on which Selarid was applied is dry.

FLEAS

Ctenocephalides felis



I see fleas on my dog or cat. Is Selarid working?

Selarid kills adult fleas and prevents flea eggs from hatching. You may occasionally see a few fleas on dogs or cats treated with Selarid but more than 98% of adult fleas are killed within 36 hours. Immature stages of the flea called pupae may be present in your pets' environment (yard, flooring,

carpet, bedding, etc.). These pupae are not killed by parasiticides (including Selarid) and as such may emerge as adult fleas. These adult fleas may hop onto your pet at anytime.

They must be exposed to Selarid on your dog or cat before being killed. It can take from 3–5 weeks (or longer depending on environmental conditions) for most fleas to complete their 4-stage life cycle (egg, larvae, pupae, and adult) and reach the adult stage before being seen on your pet. Due to the presence of immature flea stages in infested environments it can take up to 2 to 3 monthly applications for Selarid to maximally control the infestation of fleas in the environment. Once the flea population is controlled you will be less likely to see fleas.

I see ticks on my dog. Is Selarid working?

Selarid controls tick infestations only due to the American Dog Tick (*Dermacentor variabilis*), a tick commonly found on dogs. There are other common species of ticks that are not killed or controlled by Selarid. Your veterinarian can recommend appropriate products to control or kill ticks common to your area. For the control of the American Dog Tick, Selarid should be applied once a month; however, your veterinarian may recommend a second administration applied 14 days after the first dose if your dog has a heavy tick infestation and/or recommend additional tick control methods. It may take up to 5 days to kill the majority of ticks on your dog.

What are the possible side effects of Selarid?

Like all medicines, Selarid has some side effects. The most common is hair loss at the site of application with or without inflammation (redness, flaking) in cats. Other side effects reported in cats and dogs include vomiting, diarrhea with or without blood, anorexia (decreased appetite), lethargy (sluggishness), salivation, rapid breathing, pruritus (itching), urticaria (welts, hives), erythema (skin redness), ataxia (incoordination), fever and rare instances of death. There have also been rare reports of seizures in dogs.

If you have additional questions about possible side effects, talk to your veterinarian.

Can Selarid be given with other medicines?

In well-controlled clinical studies, selamectin solution was used safely in dogs and cats receiving other veterinary products such as vaccines, anthelmintics, antiparasitics, antibiotics, steroids, collars, shampoos and dips.

Tell your veterinarian about all medicines you have given your dog or cat in the past, and any medicines that you are planning to use with Selarid. This should include other medicines that you can get without a prescription. Your veterinarian may want to check that all of your dog's or cat's medicines can be given together.

How should Selarid be stored?

Selarid is flammable – Keep away from heat, sparks, open flames or other sources of ignition. Store below 86°F (30°C). After application, empty applicators can be placed in your normal household refuse for disposal.

What else should I know about Selarid?

Selarid is not for use in humans. Selarid should be kept out of reach of children. In humans, Selarid 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 Selarid should use the product with caution or consult a health care professional.

Selarid 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. In case of human ingestion contact a doctor immediately.



Selarid™

(selamectin)

Topical Parasiticide For Dogs and Cats

CAUTION: US Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION: Selarid (selamectin) Topical Parasiticide is available as a colorless to yellow, ready to use solution in single dose applicators for topical (dermal) treatment of dogs six weeks of age and older and cats eight weeks of age and older. The content of each applicator is formulated to provide a minimum of 2.7 mg/lb (6 mg/kg) of body weight of selamectin. The chemical composition of selamectin is (5Z,25S)-25-cyclohexyl-4'-O-de(2,6-dideoxy-3-O-methyl-α-L-ara-bino-hexopyranosyl)-5-demethoxy-25-de(1-methylpropyl)-22,23-dihydro-5-hydroxyiminoavermectin A_{1a}.

INDICATIONS: Selarid is recommended for use in dogs six weeks of age or older and cats eight weeks of age and older for the following parasites and indications:

Dogs: Selarid kills adult fleas and prevents flea eggs from hatching for one month and is indicated for the prevention and control of flea infestations (*Ctenocephalides felis*), prevention of heartworm disease caused by *Dirofilaria immitis*, and the treatment and control of ear mite (*Otodectes cynotis*) infestations. Selarid also is indicated for the treatment and control of sarcoptic mange (*Sarcoptes scabiei*) and for the control of tick infestations due to *Dermacentor variabilis*.

Cats: Selarid kills adult fleas and prevents flea eggs from hatching for one month and is indicated for the prevention and control of flea infestations (*Ctenocephalides felis*), prevention of heartworm disease caused by *Dirofilaria immitis*, and the treatment and control of ear mite (*Otodectes cynotis*) infestations. Selarid is also indicated for the treatment and control of roundworm (*Toxocara cati*) and intestinal hookworm (*Ancylostoma tubaeforme*) infections in cats.

WARNINGS: Not for human use. Keep out of the reach of children. In humans, Selarid 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 Selarid should use the product with caution or consult a health care professional. Selarid 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. The safety data sheet (SDS) provides more detailed occupational safety information. For a copy of the SDS or to report adverse reactions attributable to exposure to this product, call 1-866-591-5777.

Flammable - Keep away from heat, sparks, open flames or other sources of ignition.

Do not use in sick, debilitated or underweight animals (see SAFETY).

PRECAUTIONS: Prior to administration of Selarid, dogs should be tested for existing heartworm infections. At the discretion of the veterinarian, infested dogs should be treated to remove adult heartworms. Selarid is not effective against adult *D. immitis* and, while the number of circulating microfilariae may decrease following treatment, Selarid is not effective for microfilariae clearance.

Hypersensitivity reactions have not been observed in dogs with patent heartworm infections administered three times the recommended dose of selamectin solution. Higher doses were not tested.

ADVERSE REACTIONS:

Pre-approval clinical trials: Following treatment with selamectin solution, transient localized alopecia with or without inflammation at or near the site of application was observed in approximately 1% of 691 treated cats. Other signs observed rarely (0.5% of 1743 treated cats and dogs) included vomiting, loose stool or diarrhea with or without blood, anorexia, lethargy, salivation, tachypnea, and muscle tremors.

Post-approval experience: In addition to the aforementioned clinical signs that were reported in pre-approval clinical trials, there have been reports of pruritus, urticaria, erythema, ataxia, fever, and rare reports of death. There have also been rare reports of seizures in dogs (see **WARNINGS**).

DOSAGE: The recommended minimum dose is 2.7 mg selamectin per pound (6 mg/kg) of body weight. Administer the entire contents of a single dose applicator (or two applicators used in combination for dogs weighing over 130 pounds) of Selarid topically in accordance with the following tables. (See **ADMINISTRATION** for the recommended treatment intervals.)

Cats (lb)	Package color	mg per applicator	Potency (mg/mL)	Administered volume (mL)
Up to 5	Mauve	15 mg	60	0.25
5.1 – 15	Blue	45 mg	60	0.75
15.1 – 22	Taupe	60 mg	60	1.0

For cats over 22 lbs use the appropriate combination of applicators.

Dogs (lb)	Package color	mg per applicator	Potency (mg/mL)	Administered volume (mL)
Up to 5	Mauve	15 mg	60	0.25
5.1 – 10	Purple	30 mg	120	0.25
10.1 – 20	Brown	60 mg	120	0.5
20.1 – 40	Red	120 mg	120	1.0
40.1 – 85	Teal	240 mg	120	2.0
85.1 – 130	Plum	360 mg	120	3.0

For dogs over 130 lbs use the appropriate combination of applicators.

Recommended for use in dogs 6 weeks of age and older and in cats 8 weeks of age and older.

ADMINISTRATION: A veterinarian or veterinary technician should demonstrate or instruct the pet owner regarding the appropriate technique for applying Selarid topically to dogs and cats prior to first use. Remove the applicator from the outer pouch using scissors or fold along diagonal line to expose nick; tear back at nick. Hold the applicator upright. Tap the narrow part of the applicator to ensure the contents remain within the main body of the applicator. Twist or snap back the tip. To administer the product, part the hair on the back of the animal at the base of the neck in front of the shoulder blades until the skin is visible. Place the tip of the applicator on the skin and squeeze the applicator 3 or 4 times to empty its entire contents directly onto the skin in one spot. Keeping the applicator squeezed, drag it away from the liquid and lift to remove. Check the applicator to ensure that it is empty. Do not massage the product into the skin. Due to alcohol content, do not apply to broken skin. Avoid contact between the product and fingers. Do not apply when the haircoat is wet. Bathing or shampooing the dog 2 or more hours after treatment will not reduce the effectiveness of Selarid against fleas or heartworm. Bathing or shampooing the cat 24 hours after treatment will not reduce the effectiveness of Selarid against heartworm. Stiff hair, clumping of hair, hair discoloration, or a slight powdery residue may be observed at the treatment site in some animals. These effects are temporary and do not affect the safety or effectiveness of the product. Discard empty applicators in your ordinary household refuse.

Flea Control in Dogs and Cats

For the prevention and control of flea infestations, Selarid should be administered at monthly intervals throughout the flea season, starting one month before fleas become active. In controlled laboratory studies >98% of fleas were killed within 36 hours. Results of clinical field studies using selamectin solution monthly demonstrated >90% control of flea infestations within 30 days of the first dose. Dogs and cats treated with selamectin solution, including those with pre-existing flea allergy dermatitis, showed improvement in clinical signs associated with fleas as a direct result of eliminating the fleas from the animals and their environment. If the dog or cat is already infested with fleas when the first dose of Selarid is administered, adult fleas on the animal are killed and no viable fleas hatch from eggs after the first administration. However, an environmental infestation of fleas may persist for a short time after beginning treatment with Selarid because of the emergence of adult fleas from pupae.

Heartworm Prevention in Dogs and Cats

For the prevention of heartworm disease, Selarid must be administered on a monthly basis. Selarid may be administered year-round or at least within one month after the animal's first exposure to mosquitoes and monthly thereafter until the end of the mosquito season. The final dose must be given within one month after the last exposure to mosquitoes. If a dose is missed and a monthly interval between dosing is exceeded then immediate administration of Selarid and resumption of monthly dosing will minimize the opportunity for the development of adult heartworms. When replacing another heartworm preventive product in a heartworm disease prevention program, the first dose of Selarid must be given within a month of the last dose of the former medication.

Selamectin, the active ingredient in Selarid, is a macrocyclic lactone compound. These compounds effectively prevent the development of adult heartworms when administered to dogs and cats within one month of exposure to infective (*L.*) *Dirofilaria immitis* larvae. Efficacy of macrocyclic lactones decreases below 100% in dogs, however, if first administered >2 months after exposure to infective larvae. Thus, in heartworm endemic regions, delaying initiation of heartworm prevention using Selarid beyond 2 months of first exposure to infective larvae (e.g., starting puppies and kittens at >8 weeks of age), or gaps of >2 months in the administration of Selarid during periods of heartworm transmission, increases the risk of the animal acquiring heartworms. Animals with unknown heartworm history that test negative for heartworms prior to the initiation of Selarid may be harboring pre-patent infections at the time Selarid was started. Testing

such animals 3–4 months after initiation of Selarid would be necessary to confirm their negative heartworm status. At the discretion of the veterinarian, cats 6 months of age may be tested to determine the presence of existing heartworm infections before beginning treatment with Selarid. Cats already infected with adult heartworms can be given Selarid monthly to prevent further infections.

Ear Mite Treatment in Dogs and Cats

For the treatment of ear mite (*O. cynotis*) infestations in dogs and cats, Selarid should be administered once as a single topical dose. A second monthly dose may be required in some dogs. Monthly use of Selarid will control any subsequent ear mite infestations. In the clinical field trials ears were not cleaned, and many animals still had debris in their ears after the second dose. Cleansing of the infested ears is recommended to remove the debris.

Sarcoptic Mange Treatment in Dogs

For the treatment of sarcoptic mange (*S. scabiei*) in dogs, Selarid should be administered once as a single topical dose. A second monthly dose may be required in some dogs. Monthly use of Selarid will control any subsequent sarcoptic mange mite infestations. Because of the difficulty in finding sarcoptic mange mites on skin scrapings, effectiveness assessments also were based on resolution of clinical signs. Resolution of the pruritus associated with the mite infestations was observed in approximately 50% of the dogs 30 days after the first treatment and in approximately 90% of the dogs 30 days after the second monthly treatment.

Tick Control in Dogs

For the control of tick (*Dermacentor variabilis*) infestations in dogs, Selarid should be administered on a monthly basis. In heavy tick infestations, complete efficacy may not be achieved after the first dose. In these cases, one additional dose may be administered two weeks after the previous dose, with monthly dosing continued thereafter.

Nematode Treatment in Cats

For the treatment and control of intestinal hookworm (*A. tubaeforme*) and roundworm (*T. cati*) infections, Selarid should be applied once as a single topical dose.

SAFETY: Selamectin solution has been tested safe in over 100 different pure and mixed breeds of healthy dogs and over 15 different pure and mixed breeds of healthy cats, including pregnant and lactating females, breeding males and females, puppies six weeks of age and older, kittens eight weeks of age and older, and avermectin-sensitive collies. A kitten, estimated to be 5–6 weeks old (0.3 kg), died 8 ½ hours after receiving a single treatment of selamectin solution at the recommended dosage. The kitten displayed clinical signs which included muscle spasms, salivation and neurological signs. The kitten was a stray with an unknown history and was malnourished and underweight (see **WARNINGS**).

DOGS: In safety studies, selamectin solution was administered at 1, 3, 5, and 10 times the recommended dose to six-week-old puppies, and no adverse reactions were observed. The safety of selamectin solution administered orally also was tested in case of accidental oral ingestion. Oral administration of selamectin solution at the recommended topical dose in 5- to 8-month-old beagles did not cause any adverse reactions. In a pre-clinical study selamectin was dosed orally to ivermectin-sensitive collies. Oral administration of 2.5, 10, and 15 mg/kg in this dose escalating study did not cause any adverse reactions; however, eight hours after receiving 5 mg/kg orally, one avermectin-sensitive collie became ataxic for several hours, but did not show any other adverse reactions after receiving subsequent doses of 10 and 15 mg/kg orally. In a topical safety study conducted with avermectin-sensitive collies at 1, 3 and 5 times the recommended dose of selamectin solution, salivation was observed in all treatment groups, including the vehicle control. Selamectin solution also was administered at 3 times the recommended dose to heartworm infected dogs, and no adverse effects were observed.

CATS: In safety studies, selamectin solution was applied at 1, 3, 5, and 10 times the recommended dose to six-week-old kittens. No adverse reactions were observed. The safety of selamectin solution administered orally also was tested in case of accidental oral ingestion. Oral administration of the recommended topical dose of selamectin solution to cats caused salivation and intermittent vomiting. Selamectin solution also was applied at 4 times the recommended dose to patent heartworm infected cats, and no adverse reactions were observed.

In well-controlled clinical studies, selamectin solution was used safely in animals receiving other frequently used veterinary products such as vaccines, anthelmintics, antiparasitics, antibiotics, steroids, collars, shampoos and dips.

STORAGE CONDITIONS: Store below 86°F (30°C).

HOW SUPPLIED: Available in eight separate dose strengths for dogs and cats of different weights (see **DOSAGE**). Selarid for puppies and kittens is available in cartons containing 3 single dose applicators. Selarid for cats and dogs is available in cartons containing 6 single dose applicators.

Approved by FDA under ANADA # 200-663

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