

# Selarid<sup>®</sup>

(selamectin)



## TOPICAL PARASITICIDE GUARANTEE

Any veterinarian or pet owner who feels that Selarid<sup>®</sup> (selamectin) has failed to protect a dog from heartworm disease, or a cat for the internal parasites for which it is labeled, is encouraged to call Norbrook<sup>®</sup>, Inc. (dial 866-591-5777 and select option for Technical Services) to discuss the case and our Selarid Guarantee. This guarantee is available to individuals who purchased authentic product from an authorized supplier and used the product according to label directions. All claims will be evaluated as independent cases and will be subject to the terms outlined below.

The following guidelines will be used to determine eligibility for reimbursement.

### REQUIREMENTS FOR ELIGIBILITY

- Selarid was purchased from a licensed veterinarian or through an approved supplier using a valid prescription from a licensed veterinarian.
- Selarid was administered in the appropriate dose for the patient's species and weight, and was used according to label directions.
- If starting heartworm preventative for the first time, or when switching from an alternative heartworm preventative, the patient was tested and found to be negative for heartworm disease, using an antigen test, prior to starting Selarid. (Knott's and filter tests for microfilaria screening will not be considered adequate to establish heartworm negative status.)
- A dog previously diagnosed with and treated for heartworm disease must have a negative antigen test prior to starting Selarid.
- Cats must have had a negative fecal flotation prior to starting Selarid.
- Diagnosis of heartworm disease while using Selarid must be confirmed with antigen tests on two separate blood samples using two different brands of test.

### REIMBURSEMENT

- **Heartworm Disease:** Norbrook, Inc. will reimburse up to \$750 (plus the acquisition cost of melarsomine hydrochloride) toward the reasonable cost of diagnosis and treatment of any eligible dog that is determined by a licensed veterinarian to have been free of heartworm disease prior to starting Selarid and who develops heartworm disease while on Selarid. Feline heartworm cases will be evaluated on a case-by-case basis.
- **Internal Parasites:** Norbrook, Inc. will reimburse up to \$50 toward the reasonable cost of diagnosis and treatment of any eligible cat that experiences roundworms (*Toxocara cati*) or hookworms (*Ancylostoma tubaeforme*), confirmed by a fecal flotation, while using Selarid.

- For questions regarding Norbrook's Selarid Guarantee, call Norbrook, Inc. (866-591-5777 – select option for Technical Services).
- Norbrook reserves the right to modify or discontinue this program at any time for any reason.
- All claims made via distribution must be accompanied by a valid proof of purchase.

**IMPORTANT SAFETY INFORMATION:** Do not use SELARID on sick, weak or underweight cats and dogs. Use only on cats 8 weeks and older and on dogs 6 weeks and older. Prior to administration, dogs should be tested for heartworms. Side Effects may include digestive upset and temporary hair loss at application site with possible inflammation. In people, SELARID may be irritating to skin and eyes. Wash hands after use. See Package Insert for full Prescribing Information.

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# 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-cylohexyl-4'-O-de(2,6-dideoxy-3-O-methyl-α-L-arabino-hexopyranosyl)-5-demethoxy-25-de(1-methylpropyl)-22,23-dihydro-5-hydroxyiminoavermectin A<sub>10</sub>.

## 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, infected 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 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. 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<sub>3</sub>) *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

Selarid™ is a registered trademark of Norbrook Laboratories Limited Made in the UK

Manufactured by:  
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