

# Pr Selavectine

## heartworm topical solution

### Veterinary Use Only

Topical Parasiticide for Dogs and Cats

DIN 02501104, DIN 02501139

DIN 02501112, DIN 02501147

DIN 02501120, DIN 02501155

DIN 02501163, DIN 02501171

**Active ingredient:** Selamectin is a semi-synthetic compound of the avermectin class.

**Product Description:** Selavectine is available as a colorless to yellow, ready to use solution in single dose tubes for topical (dermal) treatment of dogs and cats not less than six weeks of age. The content of each tube is formulated to provide a minimum of 6 mg/kg of body weight of selamectin.

**Indications: DOGS:** For the treatment and control of flea (*Ctenocephalides canis*, *C. felis*), ear mite (*Otodectes cynotis*), sarcoptic mange mite (*Sarcoptes scabiei*) and tick (*Rhipicephalus sanguineus*) infestations, and for the prevention of heartworm disease caused by *Dirofilaria immitis*. Selavectine is also indicated as an aid in the treatment and control of roundworm (*Toxocara canis*) infections and tick (*Dermacentor variabilis*) infestations.

**CATS:** For the treatment and control of flea (*Ctenocephalides canis*, *C. felis*) and ear mite (*Otodectes cynotis*) infestations, intestinal hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections, and for the prevention of heartworm disease caused by *Dirofilaria immitis*.

**Dosage:** Selavectine is applied topically to the skin at the recommended minimum dose of 6 mg selamectin per kg of body weight, once a month.

Administer Selavectine in accordance with the following tables:

Cats (kg)	Package Color	mg per tube	Potency (mg/mL)	Administered Volume (nominal tube sizes - mL)
≤ 2.5	Orange	15 mg	60	0.25
2.6 - 7.5	Purple	45 mg	60	0.75
7.6 - 10	Pink	60 mg	60	1.0
> 10		Appropriate combination of tubes	60	Appropriate combination of tubes

Dogs (kg)	Package Color	mg per tube	Potency (mg/mL)	Administered Volume (nominal tube sizes - mL)
≤ 2.5	Orange	15 mg	60	0.25
2.6 - 5.0	Green	30 mg	120	0.25
5.1 - 10	Turquoise	60 mg	120	0.5
10.1 - 20	Red	120 mg	120	1.0
20.1 - 40	Blue	240 mg	120	2.0
40.1 - 60	Brown	360 mg	120	3.0
> 60		Appropriate combination of tubes	120	Appropriate combination of tubes

**Administration:** Remove the cap to administer the product. Administer the product directly to the skin without massaging into the site. Part the hair on the back of the animal in front of the shoulder blades until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to empty its entire contents directly onto the skin in one spot. Avoid contact between the product and fingers. Do not apply when the hair coat is wet. Bathing or shampooing the animal 2 or more hours after treatment will not reduce the efficacy of Selavectine. Discard the used tubes in the household trash.

**Contraindications:** Do not use in sick, debilitated or underweight animals.

**Cautions:** Selavectine may be safely administered to heartworm infected dogs and cats, however, it is recommended, in accordance with good veterinary practice, that all dogs ≥ 6 months of age be tested for existing heartworm infections before beginning medication with Selavectine. Cats ≥ 6 months of age in heartworm endemic areas may also be tested to determine the presence of existing heartworm infections before beginning medication with Selavectine. Selavectine is not effective against adult *D. immitis*; however, it may decrease the number of circulating microfilariae. Selavectine should be used in animals of six or more weeks of age.

**Warnings:** Keep out of the reach of children. May be irritating to skin and eyes. 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.

**Adverse Reactions:** The following adverse events are based on voluntary post-approval global adverse drug experience reporting (excluding European countries). Not all adverse events are reported. It is not always possible to reliably estimate adverse event frequency or establish a causal relationship to product exposure using this data.

The following adverse events are listed in decreasing order of reporting frequency:

- CATS: application site hair change, lack of expected efficacy, lethargy, anorexia, emesis, application site pruritus or lesion or erythema, diarrhea, ataxia and tremor.
- Product causality could not be confirmed in the majority of cases with fatal outcome.
- DOGS: lack of expected efficacy, emesis, lethargy, diarrhea, anorexia, pruritus, convulsion, application site hair change, ataxia and muscle tremor.

As with other macrocyclic lactones, the reversible neurological signs listed have been very rarely observed after the use of selamectin topical solution.

In the majority of lack of expected efficacy reports the product causality could not be confirmed. Owner's compliance and strict adherence to the product's dosage, treatment schedule and duration as well as consideration of specific parasite biology are of utmost importance in insuring success in parasite treatment and/or prevention. Collies and other herding breeds are known to be more sensitive to the macrocyclic lactone class of medications. Signs of toxicity that can be seen with overdose include: depression, hypersalivation, tremor and ataxia. Although adverse reactions may occur with the use of any pharmaceutical product, it is recommended that any sign of new illness observed during the treatment with Selavectine is thoroughly investigated.

### Efficacy:

#### Flea Control in Dogs and Cats:

If the dog or cat is already infested with fleas when the first dose of Selavectine is administered, then adult fleas on the animal are killed and no viable flea eggs are produced after the first administration. This stops flea reproduction. An environmental infestation of fleas may persist for a short time after beginning treatment with Selavectine because of the emergence of adult fleas from pupae. However, large reductions in flea infestations are observable after just one monthly treatment as flea larvae in the animal surroundings are killed or prevented from developing to adults by treatment with Selavectine.

For the lasting control of flea infestations, Selavectine should be administered at monthly intervals throughout the flea season, starting one month before fleas become active. This ensures that fleas infesting the animal are killed and that no viable flea eggs are produced by these fleas. This breaks the flea life cycle and controls flea infestations.

Results of clinical field efficacy studies using selamectin topical solution monthly demonstrated control of flea infestations and improved the clinical manifestation of flea infestations, including flea allergy dermatitis.

#### Heartworm Prevention in Dogs and Cats:

For the prevention of heartworm disease, Selavectine must be administered on a monthly basis. Selavectine 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 Selavectine 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 Selavectine must be given within a month of the last dose of the former medication.

#### Ear Mite Treatment in Dogs and Cats

For the elimination of ear mites (*O. cynotis*) in dogs and cats, Selavectine should be administered once as a single dose. A second monthly dose of Selavectine may be required to eliminate mites in some dogs. Monthly use of Selavectine will treat any subsequent ear mite infestations. Many animals treated for otocacariasis have concurrent otitis externa involving secondary yeast or bacterial infections. *O. cynotis* causes primary inflammation and pruritus of the external ear canal and predisposes to these secondary infections. Therefore, cats and dogs with otocacariasis complicated by secondary yeast and/or bacterial infections may require supportive therapy in addition to treatment with Selavectine. Cleansing of the infested ears is recommended to remove the debris.

#### Nematode Treatment in Dogs and Cats:

For the treatment and control of intestinal hookworm (*A. tubaeforme*) and roundworm (*T. cati*) infections in cats, Selavectine should be applied once as a single treatment, and monthly thereafter to control infections.

As an aid in the treatment of intestinal roundworm (*T. canis*) infections in dogs, administer two monthly treatments, and monthly thereafter to control infections.

#### Sarcoptic Mange Treatment in Dogs:

A single dose of selamectin topical solution is safe and highly efficacious against natural infestations of *S. scabiei* in dogs, however, for complete eradication two doses may be required. Monthly use of Selavectine will treat any subsequent *Sarcoptes* mite infestations.

#### Tick treatment in Dogs:

For tick (*Rhipicephalus sanguineus*, *Dermacentor variabilis*) infestations, Selavectine should be administered on a monthly basis. In heavy tick infestations, adequate 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.

### Animal Safety:

DOGS: Selamectin topical solution has been tested with no adverse reactions in dogs of over 100 different pure and mixed breeds including Collies, and in pregnant and lactating females, breeding males and females, and puppies six weeks of age and older. Selamectin topical solution was administered at 10 times the recommended dose, and no adverse effects were observed. Selamectin topical solution was also administered at 3 times the recommended dose to heartworm infected dogs, and no adverse effects were observed.

CATS: Selamectin topical solution has been tested with no serious adverse effects in cats of over 15 different pure and mixed breeds and in pregnant and lactating females, breeding males and females and kittens six weeks of age and older. Less than 1% of cats treated in the field studies had a transient alopecia at or near the site of application, possibly due to self grooming. In safety studies, selamectin topical solution was applied at 10 times the recommended dose, and no adverse effects were noted. Selamectin topical solution was also applied at 4 times the recommended dose to heartworm infected cats, and no adverse effects were observed. Accidental oral administration of Selamectin topical solution to cats may induce salivation or vomiting.

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

**Storage Conditions:** Selavectine tubes should be stored in the original carton between 15°C and 30°C.

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

**Presentation:** Available in eight dose strengths for dogs and cats of different weights.

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