

For the use of Registered Veterinary Practitioner, Hospital or Laboratory

## SELAFORTE®

(Selamectin Spot-on solution for dogs and cats)

### Composition:

#### SELAFORTE® spot on solution 12% w/v for Small Dogs (weighing 5.1 to 10 kg)

Each 0.5 ml contains:

Selamectin EP	60 mg
Butylated Hydroxytoluene IP	0.40 mg
Excipients	q.s.

#### SELAFORTE® spot on solution 12% w/v for Medium Dogs (weighing 10.1 to 20 kg)

Each 1 ml contains:

Selamectin EP	120 mg
Butylated Hydroxytoluene IP	0.80 mg
Excipients	q.s.

#### SELAFORTE® spot on solution 12% w/v for Large Dogs (weighing 20.1 to 40 kg)

Each 2 ml contains:

Selamectin EP	240 mg
Butylated Hydroxytoluene IP	1.60 mg
Excipients	q.s.

#### SELAFORTE® spot on solution 12% w/v for Extra Large Dogs (weighing 40.1 to 60 kg)

Each 3 ml contains:

Selamectin EP	360 mg
Butylated Hydroxytoluene IP	2.40 mg
Excipients	q.s.

#### SELAFORTE® spot on solution 6% w/v for Cats (weighing 2.6 to 7.5 kg)

Each 0.75 ml contains:

Selamectin EP	45 mg
Butylated Hydroxytoluene IP	0.60 mg
Excipients	q.s.

### Description:

SELAFORTE® (selamectin) Topical Parasiticide is available as ready to use solution in single dose tubes for topical (dermal) treatment of dogs six weeks of age and older and cats eight weeks of age and older. The content of each tube is formulated to provide a minimum of 6 mg/kg of body weight of selamectin.

### Pharmacology:

#### Pharmacokinetics:

In dogs, after topical spot-on administration selamectin spreads rapidly through the hair-coat

within the first 24 hours. Only a small part of the administered dose is absorbed through the skin into the bloodstream. Highest blood levels are achieved about 70 hours after administration.

In cats, the amount absorbed into blood is significantly higher, probably due to the thinner cat skin and to oral intake after grooming. As a consequence, bioavailability is much higher in cats (~75%) than in dogs (~5%).

Excretion runs faster in dogs than in cats. In both dogs and cats, most selamectin is excreted through feces and only a small amount through urine, mostly in the form of the parent molecule.

### Pharmacodynamics:

Selamectin, a macrocyclic lactone acts as agonist of the GABA (gamma aminobutyric acid) neurotransmitter in nerve cells and also binds to glutamate-gated chloride channels in nerve and muscle cells of invertebrates. In both cases it blocks the transmission of neuronal signals of the parasites, which are either paralyzed or expelled out of the body or they starve. It also affects the reproduction of some parasites by diminishing oviposition or inducing an abnormal oogenesis. Macrocyclic lactones are much less toxic to mammals (i.e. macrocyclic lactone does not cross blood-brain barrier) than to the parasites, which allow quite high safety margins for use on livestock and pets.

**Indications:** SELAFORTE® 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:

SELAFORTE® 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. SELAFORTE® is also indicated for the treatment and control of sarcoptic mange (*Sarcoptes scabiei*) and for the control of tick infestations due to *Dermacentor variabilis*.

**Cats:**

SELAFORTE® 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. SELAFORTE® is also indicated for the treatment and control of roundworm (*Toxocara cati*) and intestinal hookworm (*Ancylostoma tubaeforme*) infections in cats.

**Dosage:** The recommended minimum dose is 6 mg/kg of body weight.

Administer the entire contents of a single dose tube according to the body weight.

SELAFORTE® should be administered on a monthly basis or as recommended by a veterinarian depending on parasitic infestation.

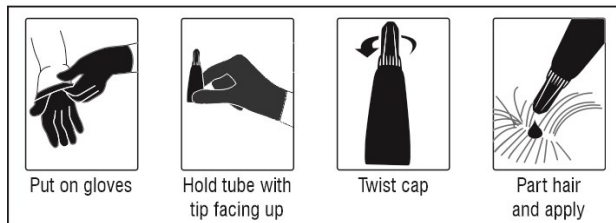
Presentation	Selamectin concentration (mg)	Administered volume (ml)
<b>Small dogs</b> (5.1 to 10kg)	60mg	0.5ml
<b>Medium dogs</b> (10.1 to 20kg)	120mg	1ml
<b>Large dogs</b> (20.1 to 40kg)	240mg	2ml
<b>Extra-large dogs</b> (40.1 to 60kg)	360mg	3ml
<b>Cats</b> (2.6 to 7.5kg)	45mg	0.75ml

For dogs over 60 kg, use the appropriate combination of tubes

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

**Administration:**

How to use:



**Step 1:** Immediately before use, Put on gloves. Hold the tube at the crimped end with the cap in an upright position (tip up). The cap should be rotated counter clockwise one full turn. The cap is designed to stay on the tube for dosing and should not be removed. The tube is open and ready for application when a breaking of the seal is felt.

**Step 2:** The pet should be standing or lying with its back horizontal during application. Part the fur at the administration site. Place the tube tip vertically against the skin at the base of the skull of the pet.

**Step 3:** Squeeze the tube and gently apply the entire contents of SELAFORTE directly to the skin at the base of the skull of the pet. Avoid applying an excessive amount of solution that could cause some of the solution to run and drip off of the pet. If a second spot is needed to avoid run off, then apply the second spot slightly behind the first spot.

Check the tube 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 SELAFORTE® against fleas or heartworm. Bathing or shampooing the cat 2 hours after treatment will not reduce the effectiveness of SELAFORTE® against fleas. Bathing or shampooing the cat 24 hours after treatment will not reduce the effectiveness of SELAFORTE® 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.

**Warnings:** Not for human use. Keep out of the reach of children.

In humans, SELAFORTE® may be irritating to skin and eyes. Individuals with known hypersensitivity to Selamectin should use the product with caution or consult a health care professional. 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.

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

Do not use in sick, debilitated or underweight animals.

**Precautions:** SELAFORTE® is not effective against adult *D. immitis* and, while the number of circulating microfilariae may decrease following treatment, SELAFORTE® is not effective for microfilariae clearance.

**Adverse Reactions:** Adverse effects are rare. Some reported adverse event includes vomiting, loose stool

or diarrhea with or without blood, anorexia, lethargy, pruritus, fever, salivation, tachypnea, and muscle tremors.

**Safety:** Selamectin has been reported safe for use in pregnant and lactating females, breeding males and females, puppies six weeks of age and older, and kittens eight weeks of age and older. Selamectin should not be used in sensitive breeds i.e. collies and related breeds.

**Presentation:**

SKU	Presentation
<b>SELAFORTE® for Small Dogs</b> (weighing 5.1 to 10 kg)	Single-dose Tube of 0.5 ml
<b>SELAFORTE® for Medium Dogs</b> (weighing 10.1 to 20 kg)	Single-dose Tube of 1 ml
<b>SELAFORTE® for Large Dogs</b> (weighing 20.1 to 40 kg)	Single-dose Tube of 2 ml
<b>SELAFORTE® for Extra Large Dogs</b> (weighing 40.1 to 60 kg)	Single-dose Tube of 3 ml
<b>SELAFORTE® for Cats</b> (weighing 2.6 to 7.5 kg)	Single-dose Tube of 0.75 ml

**Storage:** Store below 30°C. Protect from light and moisture.

**KEEP OUT OF REACH OF CHILDREN.  
HAZARDOUS TO HUMAN.**

Container Disposal: Securely wrap the tube in several layers of newspaper and discard in the trash.

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