**Revolution** (selamectin)

**Topical Parasiticide For Dogs and Cats**

**CAUTION:**

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

**DESCRIPTION:**

Revolution (selamectin) Topical Parasiticide is available as a colorless to yellowish, 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 2.7 mg/mL (6 mg/kg) of body weight of selamectin. The chemical composition of selamectin is (S,2S,2R)-2-cyclohexyl-4′-dodeca-3″-0-methyl-α-3-arboxy-benzoyl-5-dimethyl-25-(1-methylypropyl)-22,23-dihydro-5-hydroxymesanvermin A.

**INDICATIONS:**

Revolution 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**

- Revolution kills adult fleas and prevents flea eggs from hatching for one month and is indicated for the prevention of 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. Revolution also is indicated for the treatment and control of sarcoptic mange (Sarcoptes scabiei) and for the control of tick infestations due to Dermacentor variabilis.

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**Cats**

- Revolution is indicated for use in cats over 22 lbs. Use the appropriate combination of tubes.

- Revolution is indicated for use in cats over 130 lbs. Use the appropriate combination of tubes.

**WARNINGS:**

Not for human use. Keep out of the reach of children.

- In humans, Revolution may be irritating to skin and eyes. Reactions such as hives, itching and redness have been reported in humans in rare instances. Individuals with known hypersensitivity to Revolution should not use the product with or without a health care professional. Revolution contains isopropyl alcohol and the preserved 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 material safety data sheet (MSDS) provides more detailed occupational safety information. For a copy of the MSDS or to report adverse reactions attributable to exposure to this product, call 1-800-368-5288.

- 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:**

**For the administration of Revolution, dogs should be tested for existing heartworm infections. At the discretion of the veterinarian, infected dogs should be treated to remove adult heartworms. Revolution is not effective against adult _D. immitis_ and, while the number of circulating microfilariae may decrease following treatment, Revolution 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 Revolution. Higher doses were tested.**

**ADVERSE REACTIONS:**

**Pre-approval clinical trials:**

Following treatment with Revolution, 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 (≤1%) 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 which were reported in pre-approval clinical trials, there have been reports of pruritus, ataxia, muscle tremors, 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 tube for two tubes used in combination for dogs weighing over 130 pounds (22 lbs) for Revolution topicalically in accordance with the following tables. (See ADMINISTRATION for the recommended treatment intervals.)

<table>
<thead>
<tr>
<th>Cats (lb)</th>
<th>Package color</th>
<th>mg per tube</th>
<th>Potency (mg/mL)</th>
<th>Administered volume (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 5</td>
<td>Mauve</td>
<td>15 mg</td>
<td>60</td>
<td>0.25</td>
</tr>
<tr>
<td>5.1–15</td>
<td>Blue</td>
<td>45 mg</td>
<td>60</td>
<td>0.75</td>
</tr>
<tr>
<td>15.1–22</td>
<td>Teal</td>
<td>60 mg</td>
<td>60</td>
<td>1.0</td>
</tr>
<tr>
<td>For cats over 22 lbs use the appropriate combination of tubes.</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

For dogs over 130 lbs 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:**

A veterinarian or veterinary technician should demonstrate or instruct the pet owner regarding the appropriate technique for applying Revolution topicaly to dogs and cats prior to first use.

**For dogs:**

- Firmly press the cap down to puncture the seal on the Revolution tube; a clicking sound will confirm that the cap has successfully punctured the seal. Remove the cap and check to ensure that the tip of the tube is open. 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 tube on the skin and squeeze the tube 3 or 4 times to empty its entire contents directly onto the skin in one spot. Keeping the tube squeezed, drag it away from the liquid and lift to remove. 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 animal 2 or more hours after treatment will not reduce the effectiveness of Revolution. Staff hair, clumping of 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 tubes in your ordinary household refuse.

**Flea Control in Dogs and Cats**

For the prevention and control of flea infestations, Revolution 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 Revolution monthly demonstrated >90% control of flea infestations within 30 days of the first dose. Dogs and cats treated with Revolution every month, including those with pre-existing dermatitis, demonstrated improved 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 Revolution is administered, adult fleas on the animal are killed and no viable flea hatch from eggs after the first application. However, an environmental infestation of fleas may persist for a short time after beginning treatment with Revolution because of the emergence of adult fleas from pupae.

**Heartworm Prevention in Dogs and Cats**

For the prevention of heartworm disease, Revolution must be administered on a monthly basis. Revolution may be administered year-round or at least once within 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 Revolution and resumption of monthly dosing may 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 Revolution must be given within a month of the last dose of the former medication.

**Selamectin, the active ingredient in Revolution, 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 (L1) Dirofilaria immitis larvae.**

**WARNINGS:**

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**SAFETY:**

- For cats, one additional dose may be administered two weeks after the previous dose, with monthly dosing continued thereafter.

**Nematoide Treatment in Cats**

- For the treatment and control of intestinal hookworm (A. tubaeformis) and roundworm (T. cati) infestations, Revolution should be applied once as a single topical dose.

**STORAGE CONDITIONS:**

Store below 30°C (86°F).

**HOW SUPPLIED:**

Available in eight separate dose strengths for dogs and cats of different weights (see Dosing). For puppies and kittens is available in cartons containing 3 single dose tubes. Revolution for dogs and cats is available in cartons containing 6 single dose tubes.