





## SAME MEDICINE, HIGHER VALUE, MADE IN USA

Revolt® (selamectin) Topical Parasiticide is a highly affordable, once-a-month prevention answer for heartworms, fleas and a host of other parasites. Revolt® offers the same active ingredient and mode of action as the pioneer product, Revolution® Topical Solution, but at greatly reduced pricing.



# REVOLT® DEFENDS AGAINST:













DOGS

# FEATURES & BENEFITS COMPARISON

Revolt\* is recommended for use in dogs six weeks of age or older and cats eight weeks of age and older

PRODUCT FEATURES	REVOLT°	REVOLUTION°
Active ingredient: Selamectin	✓	✓
Full line comparison to pioneer product	✓	*
Manufactured in USA for secure supply chain	✓	✓
Twist-N-Apply applicator — no cap to remove/dispose	✓	
Product color coding matches pioneer for ease of CLIENT conversion	✓	✓
Available for kittens up to 5-lbs.	✓	✓
Available for puppies up to 5-lbs.	✓	✓
Weight-specific packages for exact dosing	✓	✓
Quick-drying, non-greasy topical solution	✓	✓
Monthly control of heartworm, fleas, ear mites in dogs and cats	✓	✓
Monthly control of American dog tick and sarcoptic mange in dogs	✓	✓
Treatment of roundworms and hookworms in cats	✓	✓

\*Pioneer Product

Approved by FDA under ANADA # 200-673

# PACKAGING, APPLICATION AND PRICING ADVANTAGES

- ▼ Revolt® is Specifically Designed to Offer a Full-Line Comparison to Revolution®
- **▼** Best Pricing, Always
- ✓ Safe & Secure Supply Chain Revolt® is Manufactured and Packaged in the USA
- ✓ Ease of Administration Revolt's® easy twist-to-apply design simplifies the application process, eliminating the need to remove the cap
- Revolt® Packaged for Ease of Use Like all Aurora Pharmaceutical products, improved packaging design is always a high priority. Revolt® packaging is no exception.
  - Innovative tube design ensures stability
  - Revolt's® individual packaging makes removing the tube easy
  - Product color coding matches pioneer for ease of conversion
  - Full line, weight-specific products assure your clients are applying the exact protective dose of selamectin each time

## **APPLICATION:**



1. Remove the Revolt\* tube from its protective package.

2. While holding the tube in an upright position, twist the cap to break the seal. The cap will remain on the tube.



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.

## **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 (or the appropriate combination of tubes for cats over 22 lbs. and dogs over 130 lbs.) of Revolt\* topically in accordance with the following table:

DESCRIPTION	PACKAGE COLOR	WEIGHT (lbs.)	Mg PER TUBE	POTENCY (mg/mL)	ADMIN. VOLUME (mL)
Revolt <sup>®</sup> Kitten	Rose	Up to 5	15 mg	60	0.25
Revolt <sup>®</sup> Cat	Blue	5.1 - 15	45 mg	60	0.75
Revolt <sup>®</sup> Cat	Taupe	15.1 - 22	60 mg	60	1.0
Revolt <sup>®</sup> Puppy	Rose	Up to 5	15 mg	60	0.25
Revolt <sup>®</sup> Dog	Purple	5.1 -10	30 mg	120	0.25
Revolt <sup>®</sup> Dog	Brown	10.1 - 20	60 mg	120	0.5
Revolt <sup>®</sup> Dog	Maroon	20.1 - 40	120 mg	120	1.0
Revolt <sup>®</sup> Dog	Teal	40.1 - 85	240 mg	120	2.0
Revolt <sup>®</sup> Dog	Plum	85.1 - 130	360 mg	120	3.0

# **HELPFUL TIPS**

- ➤ Do not massage Revolt® into the skin.
- ➤ Do not apply when the haircoat is wet.
- ➤ Do not apply to broken skin Revolt® 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.



- 4. Apply the tip of the Revolt\* tube directly to the skin. Squeeze the tube firmly 3 to 4 times in one spot until empty. Keep the tube compressed on the final squeeze to avoid drawing liquid back into tube. Avoid contact between Revolt\* and your fingers.
- 5. While keeping tube squeezed, drag it away from liquid and lift up to remove.
- Ensure tube is empty.



REVOLT® BREAKS THE **FLEA LIFE CYCLE** 



Adult fleas remain on the dog or cat host, feeding and producing eggs.

Adult fleas emerge from the cocoon in search of a blood meal.

Eggs fall off of the host animal and hatch within 2 to 5 days to larvae.

**Conditions Brought About by Flea Infestation Include:** • A heavy flea burden is lethal, especially to

There are over 1,900 flea species in the

world, with Ctenocephalides felis, the

cat flea, being the most troublesome for

- smaller or younger animals
- Flea Allergic Dermatitis

cats, dogs and pet owners.

- Flea Anemia
- Feline Infectious Anemia (a life-threatening blood parasite carried by fleas)
- Cat Scratch Fever/Bartonellosis (infected cat can make a person sick)
- Common Tapeworm Infection

Larvae develop into pupae inside a debris-coated. silk-like fiber cocoon (cross section).

For each flea on the host, there are many more eggs,

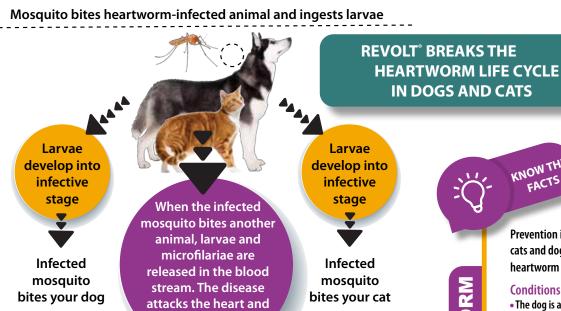
larvae, and pupae concentrated in the environment

(carpet, bedding, soil, decaying vegetation, etc.).

Larvae feed on adult flea feces which fall off the host and organic debris present in the environment.



KNOW TH



Prevention is the only means of protecting cats and dogs from the effects of heartworm disease

### **Conditions From Heartworms:**

- The dog is a natural host for heartworms, which means that they live inside the dog, mature into adults, mate and produce offspring
- Dogs have been known to harbor several hundred worms in their bodies and cause lasting damage to the heart, lungs and arteries
- Heartworm disease is a serious health issue and often goes undiagnosed in cats. Only 5% of cats are on year round heartworm protection

Treatment is needed



lungs

Prevention is preferred

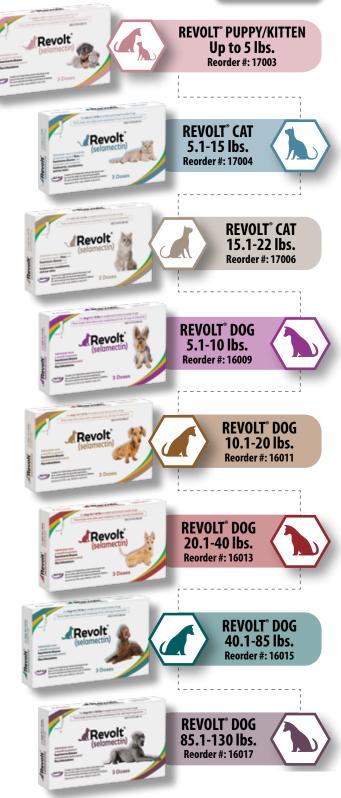
## For questions, please call 800-345-1793 or visit:

www.aurorapharmaceutical.com

### **6-PACKS**









#### Revolt® (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.

#### DESCRIPTIONS

Revolt (selamectin) Topical Parasiticide is available as a colorless to yellow, 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/lb (6 mg/kg) of body weight of selamectin. The chemical composition of selamectin is (52,255)-25-cyclohexyl-4'-0-de(5-dideoxy-3-0-methyl-cu-1-arabino-hexopyranosyl)-5-demethoxy-25-de(1-methyl-cu-2)-23-didhydro-5-hydroxylminoavermectin A<sub>1x</sub>:

#### INDICATIONS:

Revolt 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:

Revolt 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 immits, and the treatment and control of ear mite (Dtadectes cynotis) infestations. Revolt also is indicated for the treatment and control of sarcoptic mange (Sarcoptes scabier) and for the control of tick infestations due to Dermacentor variabilis.

#### Cats

Revolt kills adult fleas and prevents flea eggs from hatching for one month and is indicated for the prevention and control of flea infestations (Ctenocephaldies Felis), prevention of heartworm disease caused by Dirofilaria immitis, and the treatment and control of ear mite (Otodectes cynotis) infestations. Revolt 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, Revolt 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 Revolt should use the product with caution or consult a health care professional. Revolt contains isopropyl alcohol and the preservative butylated hydroxyloluene (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. To report suspected adverse drug events, for technical assistance or to obtain a copy of the SDS, contact Aurora Pharmaceutical at 1-888-ET3-1256 or www.aurorapharmaceutical.com. For example, and about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at www.fda.gov/reportanimalae.

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

#### ADVERSE REACTIONS:

#### Pre-approval clinical trials:

Following treatment with selamectin, 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 ( $\leq$ 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 tube (or two tubes used in combination for dogs weighing over 130 pounds) of Revolt topically in accordance with the following tables. (See **ADMINISTRATION** for the recommended treatment intervals.)

Cats (lb)	Package Color	mg per tube	Potency (mg/mL)	Administered volume (mL)
Up to 5	Rose	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 tubes

Dogs (lb)	Package Color	mg per tube	Potency (mg/mL)	Administered volume (mL)
Up to 5	Rose	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	Maroon	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 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 Revolt topically to dogs and cats prior to first use.

While holding the tube in an upright position, twist the cap to break the seal. The cap will remain on the tube. 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 of 4 times to empty it sentire content sifterity 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 dog 2 or more hours after treatment will not reduce the effectiveness of Revolt against fleas or heartworm. Bathing or shampooing the cat 2 hours after treatment will not reduce the effectiveness of Revolt against fleas. Bathing or shampooing the cat 24 hours after treatment will not reduce the effectiveness of Revolt 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 tubes in your ordinary household refuse.

#### Flea Control in Dogs and Cats

For the prevention and control of flea infestations, Revolt 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 dinicial field studies using selamectin monthly demonstrated >99% control of flea infestations within 30 days of the first dose. Dogs and cats treated with selamectin, 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 Revolt 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 Revolt because of the emergence of adult fleas from pupae.

#### **Heartworm Prevention in Dogs and Cats**

For the prevention of heartworm disease, Revolt must be administered on a monthly basis. Revolt 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 sexposure to mosquitoes. If a dose is missed and a monthly interval between dosing is exceeded then immediate administration of Revolt 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 Revolt must be given within a month of the last dose of the former medication.

Selamectin, the active ingredient in Revolt, 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 Revolt 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 Revolt 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 Revolt may be harboring pre-patent infections at the time Revolt was started. Testing such animals 3–4 months after initiation of Revolt would be necessary to confirm their negative heartworm status.

At the discretion of the veterinarian, cats  $\geq$  6 months of age may be tested to determine the presence of existing heartworm infections before beginning treatment with Revolt. Cats already infected with adult heartworms can be given Revolt monthly to prevent further infections.

#### Ear Mite Treatment in Dogs and Cats

For the treatment of ear mite (*Q. cynotis*) infestations in dogs and cats, Revolt should be administered once as a single topical dose. A second monthly dose may be required in some dogs. Monthly use of Revolt 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. scabien*) in dogs, Revolt should be administered once as a single topical dose. A second monthly dose may be required in some dogs. Monthly use of Revolt 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, Revolt 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. catt) infections, Revolt should be applied once as a single topical dose.

#### SAFETY:

Selamectin 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 lacating 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 1/2 hours after receiving a single treatment of selamectin 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 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 administered orally also was tested in case of accidental oral ingestion. Oral administration of selamectin 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, salivation was observed in all treatment groups, including the vehicle control. Selamectin also was administered at 3 times the recommended dose to heartworm infected dogs, and no adverse effects were observed.

CATS: In safety studies, selamectin 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 administration of the recommended topical dose of selamectin to acts caused salivation and intermittent wornting. Selamectin 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 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 30°C (86°F)

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

Approved by FDA under ANADA # 200-673

## Revolt® (selamectin)

Manufactured By: Aurora Pharmaceutical, Inc. Northfield, MN 55057 www.aurorapharmaceutical.com Manufactured in U.S.A.



## **ABOUT AURORA PHARMACEUTICAL**

Aurora Pharmaceutical, Inc., is a veterinary pharmaceutical product development and manufacturing company headquartered in Northfield, Minnesota. Our focus and goal is to provide customers with products that maximize livestock and companion animal health.

We understand how valuable each animal is to their owner and when an animal suffers, their caregiver shares the pain. Our veterinary products are carefully formulated to improve animal health and well-being.



Based on more than thirty years of experience, Aurora possesses unique expertise to fulfill a wide array of needs within the veterinary industry. With promising products and patents in the pipeline, Aurora is positioned to be a strong, national leader in veterinary health care.

Experienced veterinarians in our company have worked closely with animals and their caregivers. We have a unique understanding of the science behind developing healthcare solutions to an ever changing market.

# ENVIRONMENTAL AWARENESS

We take pride in the environmentally-friendly technologies we use to create high-quality products. Aurora is registered with the EPA, FDA and USDA, and is committed to complying with all regulatory requirements.

Aurora constantly improves formulations by removing harmful ingredients, while increasing efficacy of the medicine, as well as closely working with environmental agencies to continue our green manufacturing process.





