

revolution[®] PLUS

(selamectin and sarolaner topical solution)

Broad Spectrum Parasite Protection

Feature #1:	Feature #2:	Feature #3:
Broad spectrum parasite protection in one monthly dose: fleas, ticks, ear mites, heartworm disease, hookworms and roundworms.	Simple-to-apply, quick-drying, small-volume, monthly topical solution does not require gloves for application. Wash hands thoroughly after application.	Unique dual-action of selamectin and sarolaner in Revolution Plus adds an additional mechanism of action against pests that pet owners care about most.*
Benefit #1:	Benefit #2:	Benefit #3:
Protects cats and kittens (as young as 8 weeks) from 6 common parasites in one easy to use, monthly dose.	Promotes an easy routine for owners to follow without disrupting the bond with their cat.	Revolution Plus allows veterinarians to elevate cat care, and offer original Revolution customers tick protection and dual-action against fleas and ear mites.

IMPORTANT SAFETY INFORMATION:

The safe use of **Revolution Plus** has not been established in kittens less than 8 weeks old or in breeding, pregnant or lactating cats. Reported side effects in clinical trials included lethargy and anorexia. Use with caution in cats with a history of neurologic disorders. Sarolaner, one of the ingredients in Revolution Plus, is a member of the isoxazoline class, which has been associated with adverse reactions such as tremors, ataxia, and seizures. Reactions have occurred in cats with or without a history of neurologic disorders. In humans, Revolution Plus may be irritating to skin and eyes. **See Brief Summary of full Prescribing Information on page XX.**

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*vs original Revolution

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sound
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REASON 629



3 in 4 Pet Owners Prefer to use Revolution Plus¹



Veterinarians'
#1 Choice
for Cats¹



20 Years of
Proven Protection*

revolution[®] PLUS 
(selamectin and sarolaner topical solution)

¹ In a 3 way study with other leading combination products, n=20, data on file
*Revolution Plus is veterinarians' #1 trusted choice in feline parasite protection,
built upon the proven 20-year legacy protection of Revolution (selamectin).

sound byte

CHECK-OFF &
ECHO NOTES

First, always ask if a Zoetis representative has been in contact recently:

Doctor, have you recently been introduced to Revolution[®] Plus, which offers broad parasite protection available to cats in one easy-to-use monthly dose?

If **YES**, confirm and discuss benefits.

If **NO**, engage/detail the customer as the primary contact.

Confidence

Revolution[®] Plus will elevate the care you provide to cats, broadening the protection you prescribe to include ticks and adding dual-protection against fleas. You can have peace of mind dispensing Revolution Plus too because, unlike some other products, its simple application does not require owners to wear gloves, simply wash hands thoroughly after application. You can safely prescribe Revolution Plus to heartworm positive cats, and kittens as young as 8 weeks. No wonder Revolution Plus is already veterinarians' #1 choice in feline parasiticides.

Neutral invitation

Let's take a look at some basic information about Revolution Plus... The dual action of selamectin and sarolaner in Revolution Plus protects against fleas, ticks (dog, deer, Gulf Coast, and lone star), ear mites, heartworm disease, hookworms and roundworms. It is available as a low volume, fast-drying, topical monthly dose that comes in 3 sizes.

It's the customer's decision

Would you like to make Revolution Plus your first choice for cats too?

revolution PLUS

(selamectin and sarolaner topical solution)

CAUTION:

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

INDICATIONS:

REVOLUTION PLUS is indicated for the prevention of heartworm disease caused by *Dirofilaria immitis*. REVOLUTION PLUS kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment and prevention of flea infestations, the treatment and control of tick infestations with *Amblyomma americanum* (lone star tick), *Amblyomma maculatum* (Gulf Coast tick), *Dermacentor variabilis* (American dog tick), and *Ixodes scapularis* (black-legged tick), the treatment and control of ear mite (*Otodectes cynotis*) infestations, and the treatment and control of roundworm (*Toxocara cati*) and intestinal hookworm (*Ancylostoma tubaeforme*) infections for one month in cats and kittens 8 weeks and older, and weighing 2.8 pounds or greater.

CONTRAINDICATIONS:

There are no known contraindications for the use of REVOLUTION PLUS.

WARNINGS:

Human warnings:

Not for human use. Keep this and all drugs out of the reach of children.

Do not come into contact with or allow children to contact the application site until 4 hours post application.

In humans, REVOLUTION PLUS may be irritating to skin and eyes. REVOLUTION PLUS and selamectin topical solution contain isopropyl alcohol and the preservative butylated hydroxytoluene (BHT). Reactions such as hives, itching and skin redness have been reported in humans after accidental dermal contact with selamectin topical solution. Individuals with known hypersensitivity to selamectin topical solution should use caution or consult a health care professional before applying this product on a cat. **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; if wearing contact lenses, rinse the eyes first then remove contact lenses and continue to rinse for 5 – 10 minutes and seek medical attention. 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 a suspected adverse reaction, call Zoetis at 1-888-963-8471.

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

PRECAUTIONS:

Sarolaner, one of the ingredients in REVOLUTION PLUS, is a member of the isoxazoline class. This class has been associated with neurologic adverse reactions including tremors, ataxia, and seizures. Neurologic adverse reactions have been reported in cats receiving isoxazoline class drugs, even in cats without a history of neurologic disorders. Use with caution in cats with a history of neurologic disorders.

The safe use of REVOLUTION PLUS has not been evaluated in kittens less than 8 weeks of age. The safe use of REVOLUTION PLUS has not been evaluated in breeding, pregnant, or lactating cats.

ADVERSE REACTIONS:

In a field safety and effectiveness study, REVOLUTION PLUS was administered to cats with fleas. The study included a total of 430 cats (282 treated with REVOLUTION PLUS and 148 treated with imidacloprid + moxidectin once monthly for three treatments). Over the 90-day study period, all observations of potential adverse reactions were recorded. Reactions reported in the REVOLUTION PLUS group included those presented in the following table.

Adverse Reactions by Treatment Group

Adverse Reaction	REVOLUTION PLUS (n = 282)	Imidacloprid + moxidectin (n = 148)
Lethargy	12 (4.3%)	1 (0.7%)
Skin lesions*	10 (3.5%)	3 (2.0%)
Anorexia	9 (3.2%)	3 (2.0%)
Pruritus	7 (2.5%)	3 (2.0%)
Conjunctivitis	7 (2.5%)	1 (0.7%)
Sneezing	6 (2.1%)	1 (0.7%)
Administration site hair changes (alopecia)	5 (1.8%)	0 (0.0%)
Administration site lesions (scabbing)	2 (0.7%)	0 (0.0%)

*Lesions not associated with application site.

In a second field safety and effectiveness study, REVOLUTION PLUS was administered to 124 cats with ear mites. Adverse reactions in cats treated with REVOLUTION PLUS included emesis, dermatitis and eczema, and pruritus.

In a third field safety and effectiveness study, REVOLUTION PLUS was administered to 70 cats with hookworms. Adverse reactions in cats treated with REVOLUTION PLUS included diarrhea, anorexia, emesis, and lethargy.

Post-Approval Experience (2022)

The following adverse events are based on post-approval adverse drug experience reporting for REVOLUTION PLUS. Not all adverse events are reported to FDA/CVM. It is not always possible to reliably estimate the exposure using these data.

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

Application site reactions (including alopecia, lesions, erythema, and pruritus), lethargy, anorexia, vomiting, generalized pruritus, behavioral disorders (including hiding, hyperactivity, and vocalization), ataxia, muscle tremor, diarrhea, generalized alopecia, and seizure.

Contact Information

To report adverse reactions call Zoetis Inc. at 1-888-963-8471. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>.

ANIMAL SAFETY:

Margin of Safety Studies: One exploratory and two pivotal margin of safety studies were conducted with REVOLUTION PLUS. In the first study, REVOLUTION PLUS was applied topically to kittens eight weeks of age at doses of 12/2 (selamectin/sarolaner) mg/kg (1X), 36/6 mg/kg (3X), 45/7.5 mg/kg (3.75X), and 60/10 mg/kg (5X) every 28 days for eight consecutive doses. One female cat in the 3.75X group was found dead on study day 115. The cause was determined to be hemorrhage in multiple tissues secondary to a low platelet count. The role of the drug in contributing to this event is undetermined. No significant changes related to REVOLUTION PLUS were observed among the remaining cats for physical examination, body weight, clinical pathology (hematology, coagulation, and serum chemistry), gross pathology, histopathology or organ weights.

In the second study, REVOLUTION PLUS was applied topically to cats 9 months of age at doses of 1X, 3X, and 5X every 28 days for six consecutive doses. Cosmetic changes at the application site occurred sporadically in all treatment groups and included wet appearance and dried white material. Hair loss at the dose site was also noted in two cats in the 1X group and one cat in the 5X group within 1-8 days after the fourth dose administered on day 84. No significant changes related to REVOLUTION PLUS were observed for physical examination, body weight, clinical pathology (hematology, coagulation, and serum chemistry).

During an exploratory margin of safety study, one cat in the 60 mg/kg/ 10 mg/kg (selamectin/sarolaner) group (5X dose group) experienced piloerection, tremors, and mydriasis approximately 24 hours after receiving the third monthly dose of the combination. Signs resolved without treatment within 2 hours. This cat completed the study, receiving 3 subsequent 5X doses with no abnormal observations.

Oral safety study: The safety of REVOLUTION PLUS administered orally to kittens was tested in case of accidental oral ingestion. Oral administration of the highest recommended topical dose of REVOLUTION PLUS to kittens resulted in transient lower food consumption and clinical findings of emesis, soft feces, and salivation. In one male, mild tremor was observed and resolved within 3 hours after dosing; the same cat demonstrated reduced activity approximately 6 hours after dosing.

Heartworm Positive Cat Safety of Selamectin: Selamectin is the active ingredient in REVOLUTION PLUS that prevents heartworm disease in cats; it has been shown that the addition of sarolaner does not interfere with this activity. In a safety study in which selamectin topical solution was applied at 4 times the recommended dose to patent heartworm infected cats, no adverse reactions were observed.

Field safety: In three well-controlled field studies, REVOLUTION PLUS was used concurrently with other medications, such as vaccines, cestocidal anthelmintics, antibacterials, sedatives, anesthetics, opioid analgesics, corticosteroids, and non-steroidal anti-inflammatories. No adverse reactions were associated with the concurrent use of REVOLUTION PLUS and other medications.

STORAGE CONDITIONS:

Store at or below 30°C (86°F).

HOW SUPPLIED:

Available in three separate dose strengths for cats of different weights (see **DOSAGE AND ADMINISTRATION**). REVOLUTION PLUS is available in cartons containing one, three, or six single dose tubes. The amount of liquid in tube varies for each weight range (2.8 - 5.5 lbs, 5.6 - 11 lbs, 11.1- 22 lbs). Tubes are never completely filled.

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