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PROGRAM[®] FLAVOR TABS[™]

Novartis

(Lufenuron)

DIN: 02238928 (90 mg), 02238925 (204.9 mg), 02238926 (409.8 mg)

PROGRAM Flavor Tabs are once-a-month tablets that control flea infestations on dogs by interrupting the flea life cycle at the egg and larval stage.

INTRODUCTION: Novartis Animal Health encourages you to take time to read this package insert which describes the once-a-month use of PROGRAM (lufenuron) Flavor Tabs for flea prevention and control.

DESCRIPTION: The active ingredient in PROGRAM Flavor Tabs is lufenuron (N-[2, 5-dichloro-4-(1, 1, 2, 3, 3, 3-hexafluoropropoxy)-phenylaminocarbonyl]-2, 6-difluorobenzamide).

INDICATIONS: PROGRAM Flavor Tabs are indicated for use in the control of flea infestations on dogs and in their habitat. PROGRAM works by interrupting the flea life cycle, thereby preventing the build-up of flea infestations on dogs and in their surroundings. PROGRAM is indicated for use in dogs six weeks of age and older.

Treatment should be initiated at least one month before the onset of the flea season and continued throughout the entire flea season to prevent the build up of a flea infestation.

PROGRAM Flavor Tabs are also indicated for control of active mid-season flea infestations. However, in this situation, flea adulticides should be used concurrently at labelled rates for the first 6-8 weeks. This provides time for PROGRAM to impact flea population dynamics by interrupting the life cycle.

DOSAGE: PROGRAM Flavor Tabs are to be administered orally, once a month, to dogs six weeks of age and older, at the recommended minimum dosage rate of 10 mg lufenuron per kilo of body weight. See the recommended dosage schedule below:

Recommended Dosage Schedule:

Weight of Dog	Lufenuron per tablet	Package Colour	Tablet Imprint
Up to 9 kg	90 mg	Red	CGV/ACA
9 to 21 kg	204.9 mg	Yellow	CGV/GBG
21 to 41 kg	409.8 mg	White	CGV/DDD

Dogs over 41 kg should be provided the appropriate combination of tablets.

ADMINISTRATION: PROGRAM Flavor Tabs must be administered monthly, throughout the entire flea season. In areas where fleas are prevalent, mainly during the summer months, the first dose should be administered before the onset of the flea season. Treatment should continue year-round in areas where fleas are present throughout the year. Discontinuation of the PROGRAM regimen may result in flea reinfestation from sources outside the pet's immediate environment.

When using PROGRAM Flavor Tabs for control of active mid-season flea infestations, flea adulticidal products should be used concurrently for the first 6-8 weeks.

PROGRAM FLAVOR TABS SHOULD BE ADMINISTERED ON A FULL STOMACH. TO ENSURE ADEQUATE DRUG ABSORPTION, A FULL MEAL SHOULD BE INGESTED IMMEDIATELY PRIOR TO ADMINISTRATION OF TABLETS.

As an alternative to direct dosing, the tablets can be hidden in food or a treat. Watch the dog closely following dosing to be sure the entire dose has been consumed. In case of doubt, it is safe to readminister the entire dose.

ALL DOGS AND CATS INHABITING THE SAME HOUSEHOLD MUST RECEIVE PROGRAM TABLETS (DOG) OR PROGRAM SUSPENSION OR INJECTABLE (CAT). FAILURE TO TREAT ALL PETS IN THE HOUSEHOLD MAY RESULT IN SUBOPTIMAL FLEA CONTROL CAUSED BY REINFESTATION FROM UNTREATED ANIMALS.

Discontinuation of treatment with PROGRAM prior to the end of the flea season may result in flea infestations from sources outside the pet's immediate surroundings.

PROGRAM SHOULD BE USED AS PART OF A COMPREHENSIVE FLEA CONTROL PLAN UNDER THE DIRECTION OF A VETERINARIAN.

FLEA INFESTATIONS ON DOGS AND TREATMENT WITH PROGRAM: Fleas are the most important ectoparasite on dogs and cats. Fleas are not only annoying pests to you and your pet, but also pose a significant health risk to your dog. Tapeworm parasites are transmitted by fleas, and dogs may develop an allergic dermatitis from flea bites.

PHARMACOLOGY: Lufenuron, the active ingredient of PROGRAM, belongs to the chemical group of benzoylphenylurea compounds. These compounds are classified as insect development inhibitors which interfere with the transport process involved in polymerization of chitin or in the deposition of chitin chains. Chitin is the principal component of the flea egg case and cuticle

that forms the exoskeleton of larval stages and adult fleas. Most affected flea eggs fail to hatch, and of those that do hatch, surviving larval stages fail to develop.

The development-inhibiting effect of this drug occurs when the adult flea is exposed through the bloodmeal to lufenuron present in the animal's blood. Eggs and larvae from adult fleas exposed to lufenuron in this manner fail to develop properly and die. Because female fleas must feed on blood before they can lay eggs, entire populations of immature life stages are eliminated, resulting in flea control.

Lufenuron has no direct effect on mature fleas since they have fully developed exoskeletons. In order to control existing adult flea infestations, adulticidal products should be used concurrently for the first 6-8 weeks while PROGRAM is exerting its life-cycle disrupting effect.

SAFETY: PROGRAM Flavor Tabs have a wide margin of safety in dogs.

PROGRAM has been tested safely in dogs, including pregnant females, breeding males and females, and puppies. In well controlled clinical studies, PROGRAM was used safely in dogs, many of which received other commonly used veterinary products such as vaccines, anthelmintics, antibiotics, steroids, flea collars, insecticide shampoos and dips.

Breeding studies in laboratory beagles demonstrated no adverse responses in either the parental generation or in the birth and survival rate of their progeny following exposure to high doses of lufenuron (in excess of 3 times the recommended minimum dose of 10 mg/kg body weight) given *daily* from 90 days prior to mating, during gestation, whelping and through weaning.

In a 10 month chronic study, dogs dosed at 2x, 6x and 10x the labelled dose of lufenuron for three consecutive days each month, demonstrated no adverse clinical reactions, hematological, blood chemistry or histopathological effects. In studies where lufenuron was administered concomitantly with commonly used organophosphate, carbamate, or pyrethroid insecticide products for fleas, no demonstrated side effects could be attributed to lufenuron. A tolerability study at 20x the label dose in eight-week old puppies demonstrated no adverse treatment related effects.

PHARMACOKINETICS: Lufenuron administered orally to the animal is absorbed through the gastrointestinal tract and circulates in the blood. Following administration, lufenuron is distributed from the vascular compartment to adipose tissue. It is released steadily back into the blood, thus maintaining levels above the minimum effective concentration between monthly treatments.

WARNING: Keep out of reach of children. If accidentally swallowed, call a physician.

PRESENTATION: PROGRAM Flavor Tabs are available in three sizes (see Dosage section) containing 90, 204.9 and 409.8 mg active ingredient per tablet for oral administration to dogs and puppies six weeks of age and older.

They are formulated according to body weight. Each tablet size is available in a colour coded package of 6 tablets which are packaged in 10 per display carton.

PROGRAM Suspension is supplied separately for cats as a once-a-month liquid suspension or a 6-month injectable liquid suspension in convenient dispensers. Since the minimum recommended dose of PROGRAM for dogs is different from the recommended dose for cats, please consult your package insert for detailed directions.

STORAGE CONDITIONS: PROGRAM (lufenuron) Flavor Tabs should be stored at room temperature, between 15-30°C.

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