

Flea-Lix™

(nitenpyram tablets)

Felixvet Inc.

Flea-Lix kills adult fleas and is indicated for the treatment of flea infestations on dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older.

Product	Strength	Pack Size
Flea-Lix (nitenpyram tablets)	11.4 mg (Cat)	06 Tablets - in a Blister Pack
	11.4 mg (Dog)	06 Tablets - in a Blister Pack
	57.0 mg (Dog)	06 Tablets - in a Blister Pack

Features and benefits

- Therapeutically equivalent to the pioneer drug, the same safety and efficacy
- Tablets are available in two strengths - 11.4 mg and 57.0 mg





Flea-Lix™ (nitenpyram tablets)

Flea-Lix is an oral tablet for dogs, puppies, cats and kittens **2 pounds of body weight or greater and 4 weeks of age and older.**

Active Ingredient

Flea-Lix contains 11.4 or 57.0 mg of nitenpyram, which belongs to the chemical class of neonicotinoids. Nitenpyram kills adult fleas.

Warnings

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

Keep Flea-Lix in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

Directions

Flea-Lix kills adult fleas and are indicated for the treatment of flea infestations on dogs, puppies, cats and kittens **2 pounds of body weight or greater and 4 weeks of age and older.**

A single dose of Flea-Lix should kill the adult fleas on your pet. If your pet gets re-infested with fleas, you can safely give another dose as often as once per day.

To give Flea-Lix place the pill directly in your pet's mouth or hide it in food. If you hide the pill in food, watch closely to make sure your pet swallows the pill. If you are not sure that your pet swallowed the pill, it is safe to give a second pill.

Treat all infested pets in the household. Fleas can reproduce on untreated pets and allow infestations to persist.

Dosage

Flea-Lix should be administered according to the following schedule.

Weigh your pet prior to administration to ensure proper dosage. Do not administer to pets under 2 pounds.

Recommended Dosage Schedule

Species	Body Weight	Dose	Nitenpyram Per Tablet
Dog or Cat	2-25 lbs.	One Tablet	11.4 mg
Dog	25.1-125 lbs.	One Tablet	57.0 mg

Adverse Reactions

Pre-approval laboratory and clinical studies showed that nitenpyram tablets are safe for use in dogs and cats, puppies and kittens **2 pounds of body weight or greater and 4 weeks of age and older.** (See Post-Approval Experience section).

Post-Approval Experience (Rev. 2011):

The following adverse events are based on post-approval adverse drug experience reporting. Not all adverse reactions are reported to FDA CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using this data. The following adverse events are listed in decreasing order of reporting frequency.

CATS: hyperactivity, panting, lethargy, itching, vocalization, vomiting, fever, decreased appetite, nervousness, diarrhea, difficulty breathing, salivation, incoordination, seizures, pupil dilation, increased heart rate, and trembling.

DOGS: lethargy/depression, vomiting, itching, decreased appetite, diarrhea, hyperactivity, incoordination, trembling, seizures, panting, allergic reactions including hives, vocalization, salivation, fever, and nervousness.

The frequency of serious signs, including neurologic signs and death, was greater in animals under 2 pounds of body weight, less than 8 weeks of age, and/or reported to be in poor body condition. In some instances, birth defects and fetal/neonatal loss were reported after treatment of pregnant and/or lactating animals.

Contact Information

Contact Felix Pharmaceuticals Private Limited at 1-833-571-1525 or www.felixvet.com. To report suspected adverse drug experiences, contact Felix Pharmaceuticals Private Limited at 1-833-571-1525. For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>

To obtain a Safety Data Sheet(s), contact Felix Pharmaceuticals Private Limited at 1-833-571-1525.

Other Information

Flea-Lix begins working within 30 minutes. In studies, nitenpyram achieved greater than 90% effectiveness against adult fleas on dogs within 4 hours and cats within 6 hours.

Flea-Lix is safe for pregnant or nursing dogs and cats (See Post-Approval Experience section).

When using this product, you may notice that your dog or cat will start scratching itself as fleas begin to die. The scratching behavior is temporary and is a reaction to the fleas, not the drug. In cats and dogs, this may present as transient signs of hyperactivity, panting, vocalization and excessive grooming/licking.

Flea-Lix kills adult fleas that cause flea allergy dermatitis (FAD).

Flea-Lix may be used together with other products, including heartworm preventives, corticosteroids, antibiotics, vaccines, de-worming medications, shampoos and other flea products.

Flea Infestations on Dogs and Cats

In addition to the common nuisance irritations associated with infestations, fleas can be responsible for skin conditions in your pet such as flea allergy dermatitis (FAD) in the dog and miliary dermatitis in the cat. Also, fleas transmit other parasites, including tapeworms. The control of flea infestations is important to your pet's health and also reduces the problems associated with these parasites.

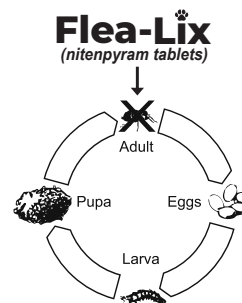
Flea-Lix does not have an effect on fleas in the pet's environment. You may need to treat more than one time because immature fleas in and around the home will continue to develop into adults that can reinfest your pet.

The following diagram illustrates the flea's life cycle and where Flea-Lix works:

Life Cycle of the Flea

Fleas can be a problem because they reproduce so rapidly. A single female flea may produce up to 2,000 eggs over her lifetime. Eggs hatch and can develop into adults within only three weeks. Adult female fleas feed by ingesting blood from your pet and subsequently lay eggs, which drop off your pet's coat. Within days, larvae hatch from the eggs and live undetected in your pet's surroundings, such as the carpet, bedding and other protected areas. Flea larvae spin a cocoon, and, when appropriately stimulated, a young adult flea emerges and jumps onto your pet to continue the life cycle. When these new fleas are seen on your pet, treat with Flea-Lix.

After reading this insert, if you have any questions about flea control or medical problems associated with flea infestations, consult your veterinarian, who is your pet's health care expert.



Storage Conditions: Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Questions? Comments? Please Call 1-833-571-1525

For technical assistance or to report a suspected adverse experiences please call 1-833-571-1525

Approved by FDA under ANADA # 200-858

Distributed by:

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Manufactured in India

Neutral Code No. MP/DRUGS/25/90/2020

Rev. July 2026

Felix