

PROGRAM 6 MONTH FOR CATS- lufenuron injection, suspension
Elanco US Inc.

PROGRAM
(LUFENURON)

6 Month Injectable for Cats

The six-month injection that controls flea populations in cats.

Caution

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

Description

PROGRAM (lufenuron) 6 Month Injectable for Cats is available in two syringe sizes for subcutaneous administration to cats and kittens according to their weight (See Dosage). Each preloaded syringe is formulated to provide 4.54 mg/pound (10 mg/kg) body weight of lufenuron. The active ingredient of PROGRAM 6 Month Injectable for Cats is lufenuron, a benzoylphenyl-urea derivative with the following chemical composition: N-[2,5-dichloro-4-(1,1,2,3,3,3-hexafluoropropoxy)-phenylaminocarbonyl]-2,6-difluorobenzamide. Benzoylphenyl-urea compounds, including lufenuron, are classified as insect development inhibitors (IDIs).

Mode of Action

Lufenuron, the active ingredient of PROGRAM 6 Month Injectable for Cats, is an insect development inhibitor which breaks the flea life cycle by inhibiting egg development. Lufenuron's mode of action is interference with chitin synthesis, polymerization and deposition. Lufenuron has no effect on adult fleas.

After biting a lufenuron-treated cat, the female flea ingests a blood meal containing lufenuron which is subsequently deposited in her eggs. Lufenuron prevents flea eggs from hatching and developing into adults and thus controls flea populations by breaking the life cycle. (See Efficacy.)

Indications

PROGRAM 6 Month Injectable for Cats is indicated for use in cats, six weeks of age and older, for the control of flea populations.

Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. Concurrent use of insecticides may be necessary for adequate control of adult fleas.

Warning

Do not use in dogs. A severe local reaction may occur in dogs that is not seen in cats.

Precautions

The safety of PROGRAM 6 Month Injectable for Cats in reproducing animals has not been established.

PROGRAM 6 Month Injectable for Cats breaks the flea life cycle by inhibiting egg development. However, pre-existing flea populations may continue to develop and emerge after treatment with PROGRAM 6 Month Injectable for Cats. Based on results of clinical studies, this emergence generally occurs during the first 30-60 days. Therefore, noticeable control may not be observed until several

weeks after dosing when a pre-existing infestation is present. Cooler geographic areas may have longer lag periods due to a prolonged flea life cycle. Insecticides may be used concurrently depending on the severity of the infestation.

Efficacy

Laboratory and clinical trials have shown that PROGRAM 6 Month Injectable for Cats is a safe, effective and convenient method to control flea populations. A single dose provides long-lasting control for a full 6 months.

In laboratory studies, PROGRAM 6 Month Injectable for Cats provided a cumulative percent control of egg development of 94.8% and 97.7% beginning 14 days post-treatment through six months post-treatment in the dose titration and dose confirmation studies, respectively. There was a 2-3 week “induction phase” in these studies before significant effects on flea reproduction were seen.

PROGRAM 6 Month Injectable for Cats was effective in controlling flea populations when administered to 183 pet cats in a clinical setting. At study initiation, treated cats averaged 43 fleas per cat. Six months post-injection these cats averaged 11 fleas per cat.

Safety

PROGRAM 6 Month Injectable for Cats has been used and tested safely in over sixteen breeds of cats, including females, males and kittens. In well-controlled clinical trials, 294 cats were treated with lufenuron. PROGRAM 6 Month Injectable for Cats has also been safely used in cats receiving frequently used veterinary products such as vaccines, anthelmintics, antibiotics, steroids and insecticides.

The acute toxicity of injectable lufenuron was evaluated by administering 100 mg/kg bw, 10x the recommended 10 mg/kg bw dose rate, to adult cats. The potential cumulative toxicity of 1x and 3x the 10 mg/kg six month use rate of lufenuron injectable in 2 week old kittens was evaluated over a two month period. Other than injection site reactions (see below), no clinical signs of toxicity were reported in these studies.

Cumulative toxicity of injectable lufenuron in 2 month old cats was evaluated by administering 1, 3, or 5x the six-month dose three times during the 6 month study. This equates to cumulative doses of 3X, 9X, and 15X, respectively. Other than injection site reactions (see below), no clinical signs of toxicity were reported in these studies. Heinz body inclusions were present in all the control and treated cats, however, erythrocytes in the 50 mg/kg (15x cumulative dose) group had slightly elevated levels of Heinz bodies at 3-6 months.

The following injection site reactions were noted in these laboratory studies. Transient, minor discomfort was noted in some kittens and cats upon injection. Small raised areas at the injection sites, presumed to be deposits of lufenuron, were seen immediately after administration and persisted in some cases for the duration of the studies. This response at the injection site correlated microscopically with acute to granulomatous inflammation and fibrosis. Older injection sites showed less inflammation which indicates these effects may resolve with time. No neoplastic transformations were found. (See Adverse Reactions.)

Dosage

PROGRAM 6 Month Injectable for Cats is injected subcutaneously once every six months at the recommended minimum dosage of 4.54 mg lufenuron per pound (10 mg/kg) of body weight.

Recommended Dosage Schedule

| <u>Body Weight</u> | <u>Syringe Size</u> | <u>Lufenuron Dose</u> |
|-------------------------|---------------------|-----------------------|
| Up to 8.8 lbs. (4.0 kg) | Small (0.4 ml) | 40 mg |

8.9 lbs. to 17.6 lbs. (4.1 to 8.0 kg)

Large (0.8 ml)

80 mg

Administration

Administer PROGRAM 6 Month Injectable for Cats subcutaneously using standard injection technique. Before administration, shake well to thoroughly mix the sterile suspension. Remove the needle guard and subcutaneously inject the entire contents of the syringe. **Do not inject intramuscularly.** The empty syringe should be disposed of in an approved manner.

To ensure the greatest benefits from the use of PROGRAM 6 Month Injectable for Cats, it is important to treat all cats within a household. All dogs within the household should be treated with lufenuron tablets. Untreated dogs and cats may develop infestations which could reduce the overall flea control within a household.

Do not administer this product to dogs.

Adverse Reactions

The following adverse reactions were observed in clinical field trials with PROGRAM 6 Month Injectable for Cats: pain on injection, injection site lumps/granulomas, vomiting, listlessness/lethargy and anorexia.

Histologic examination of one cat's injection site lump showed evidence of inflammation surrounding an area of necrosis with marked proliferation of fibrous connective tissue. In another cat, granulomatous inflammation was noted which included non-pleomorphic fibrocytes and fibroplasia.

How Supplied

PROGRAM 6 Month Injectable for Cats is available in 0.4 ml and 0.8 ml unit dose syringes, formulated according to the weight of the cat. Unit dose packs are available in packages of 10 syringes per carton.

Storage Conditions

PROGRAM 6 Month Injectable for Cats should be stored at room temperature between 59° and 86 °F (15-30 °C).

NADA# 141-105, Approved by FDA

Manufactured for:

Elanco US Inc.

Greenfield, IN 46140, USA Product of Switzerland

Elanco, Program and the diagonal bar are trademarks owned or licensed by Eli Lilly and Company, its subsidiaries or affiliates.

*Elanco*_{tm}

Principal Display Panel - Program 6 Months Injectable 40 mg Syringe Label

PROGRAMTM

(LUFENURON)

6 MONTH

INJECTABLE

Controls flea populations

(see package insert)

40 mg

up to
8.8 lbs

Shake well

Elanco

FOR CATS ONLY



Principal Display Panel - Principal Display Panel - Program 6 Months Injectable 40 mg Carton Label

FOR CAT

TREATMENT ONLY

Elanco[™]

PROGRAM[™]

(LUFENURON)

**6 MONTH
INJECTABLE
FOR CATS**

40 mg.

up to 8.8 lbs.

Net Contents: Each syringe contains
40 mg LUFENURON in 0.4 mL

Contents: 10 syringes

NADA# 141-105, Approved by FDA

Caution: Federal (USA) law restricts this drug
to be used by the order of a licensed veterinarian.

**Keep this and all drugs out
of the reach of children**

FOR CAT
TREATMENT ONLY



Batch number:
Expiry:

PROGRAM™ 6 MONTH INJECTABLE FOR CATS

(LUFENURON) 40 mg. up to 8.8 lbs.



Net Contents: Each syringe contains 40 mg LUFENURON in 0.4 mL.
Contents: 10 syringes

Caution: Federal (USA) law restricts this drug to be used by the order of a licensed veterinarian.

Keep this and all drugs out of the reach of children

NADA# 141-105, Approved by FDA

PROGRAM™ 6 MONTH INJECTABLE FOR CATS

(LUFENURON)



SH100061AMX 311288



The six-month injection that controls flea populations in cats. Recommended for cats up to 8.8 lbs.

PROGRAM™ 6 MONTH INJECTABLE FOR CATS

(LUFENURON)



READ THE ENCLOSED INSERT BEFORE USING THIS PRODUCT

Administration:

Administer PROGRAM 6 Month Injectable subcutaneously using standard injection technique. Before administration, shake the syringe well to thoroughly mix the sterile suspension. Remove the needle guard and subcutaneously inject the entire contents of the syringe. **Do not inject intramuscularly.** The empty syringe should be disposed of in an approved manner. Do not reuse syringes.

To ensure the greatest benefits from the use of PROGRAM 6 Month Injectable, it is important to treat all cats in the household. All dogs within the household should be treated with lufenuron tablets. Untreated dogs and cats may develop infestations which could reduce the overall flea control within a household.

Precautions: Do not use this product in dogs. Do not use in kittens less than 6 weeks of age.

Storage Conditions: PROGRAM 6 Month Injectable should be stored at room temperature between 59° & 86°F (15°-30°C).

Manufactured for:
Elanco US Inc.
Greenfield, IN 46140, USA
Product of Switzerland

Elanco, Program and the diagonal bar are trademarks owned or licensed by Eli Lilly and Company, its subsidiaries or affiliates.

PROGRAM™ 6 MONTH INJECTABLE FOR CATS

(LUFENURON)



Principal Display Panel - Program 6 Months Injectable 80 mg Syringe Label

PROGRAM™
(LUFENURON)

6 MONTH INJECTABLE

Controls flea populations

(see package insert)

80 mg

8.9 lbs.
to 17.6 lbs

Shake well

Elanco

FOR CATS ONLY



Principal Display Panel - Principal Display Panel - Program 6 Months Injectable 90 mg Carton Label

FOR CAT

TREATMENT ONLY

Elanco™

PROGRAM™

(LUFENURON)

**6 MONTH
INJECTABLE
FOR CATS**

80 mg.

8.9 to 17.6 lbs.

Net Contents: Each syringe contains
80 mg LUFENURON in 0.9 mL

Contents: 10 syringes

NADA# 141-105, Approved by FDA

Caution: Federal (USA) law restricts this drug
to be used by the order of a licensed veterinarian.

**Keep this and all drugs out
of the reach of children**

FOR CAT
TREATMENT ONLY

Elanco

Batch number:

Expiry:

PROGRAM™ 6 MONTH INJECTABLE FOR CATS
(LUFENURON) 80 mg.
8.9 to 17.6 lbs.



PROGRAM™ 6 MONTH INJECTABLE FOR CATS
(LUFENURON)

Net Contents: Each syringe contains 80 mg LUFENURON in 0.8 mL
Contents: 10 syringes
NADA# 141-105, Approved by FDA

Caution: Federal (USA) law restricts this drug to be used by the order of a licensed veterinarian.
Keep this and all drugs out of the reach of children

6 Month Injectable

6 Month Injectable

88211C XWZ9290001HS

6 Month Injectable



The six-month injection that controls flea populations in cats. Recommended for cats 8.9 lbs. to 17.6 lbs.

PROGRAM™ 6 MONTH INJECTABLE FOR CATS
(LUFENURON)

Elanco



READ THE ENCLOSED INSERT BEFORE USING THIS PRODUCT

Administration:

Administer PROGRAM 6 Month Injectable subcutaneously using standard injection technique. Before administration, shake the syringe well to thoroughly mix the sterile suspension. Remove the needle guard and subcutaneously inject the entire contents of the syringe. **Do not inject intramuscularly.** The empty syringe should be disposed of in an approved manner. Do not reuse syringes.

To ensure the greatest benefits from the use of PROGRAM 6 Month Injectable, it is important to treat all cats in the household. All dogs within the household should be treated with lufenuron tablets. Untreated dogs and cats may develop infestations which could reduce the overall flea control within a household.

Precautions: Do not use this product in dogs. Do not use in kittens less than 6 weeks of age.

Storage Conditions: PROGRAM 6 Month Injectable should be stored at room temperature between 59° & 86°F (15°-30°C).

Manufactured for:
Elanco US Inc.
Greenfield, IN 46140, USA
Product of Switzerland

Elanco, Program and the diagonal bar are trademarks owned or licensed by Eli Lilly and Company, its subsidiaries or affiliates.

Elanco

PROGRAM™ 6 MONTH INJECTABLE FOR CATS
(LUFENURON)

6 Month Injectable

6 Month Injectable

PROGRAM 6 MONTH FOR CATS

lufenuron injection, suspension

Product Information

| | | | |
|--------------------------------|--------------------------|---------------------------|------------------|
| Product Type | PRESCRIPTION ANIMAL DRUG | Item Code (Source) | NDC:58 198-50 20 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| LUFENURON (UNII: 1R754M49 18) (LUFENURON - UNII:1R754M49 18) | LUFENURON | 100 mg in 1 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---------------------|------------------------------|----------------------|--------------------|
| 1 | NDC:58 198 -5020 -1 | 10 in 1 CARTON | | |
| 1 | | 0.4 mL in 1 SYRINGE, PLASTIC | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NADA | NADA141105 | 03/13/1998 | |

PROGRAM 6 MONTH FOR CATS

lufenuron injection, suspension

Product Information

| | | | |
|--------------------------------|--------------------------|---------------------------|------------------|
| Product Type | PRESCRIPTION ANIMAL DRUG | Item Code (Source) | NDC:58 198 -5025 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| LUFENURON (UNII: 1R754M49 18) (LUFENURON - UNII:1R754M49 18) | LUFENURON | 100 mg in 1 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---------------------|------------------------------|----------------------|--------------------|
| 1 | NDC:58 198 -5025 -2 | 10 in 1 CARTON | | |
| 1 | | 0.8 mL in 1 SYRINGE, PLASTIC | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NADA | NADA141105 | 03/13/1998 | |

Labeler - Elanco US Inc. (966985624)

Revised: 3/2018

Elanco US Inc.