

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

NATURE/TYPE: Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Program Tablets 409.8 mg

2. STATEMENT OF ACTIVE SUBSTANCES

Lufenuron 409.8 mg

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

Net contents: 6 tablets

5. TARGET SPECIES

Tablets for dogs weighing between 21 and 80 kg

6. INDICATION(S)

Monthly oral treatment for the prevention and long term control of flea infestations in dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Please read the label and enclosed leaflet completely before use

Administer one tablet monthly for dogs 21 to 40 kg.

Administer two tablets monthly for dogs 41 to 80 kg.

Directions for use

It is essential that all cats and dogs in the household (except unweaned kittens or puppies) are treated with PROGRAM. For cats use PROGRAM Suspension and for dogs use PROGRAM tablets. PROGRAM must be given with a main meal on the same date each month. Either give with a small part of the food before the rest of the meal is offered, or give by mouth immediately after feeding.

Before fleas are seen on the dog

Where fleas are not seen on the dog, start giving PROGRAM two months before flea activity is anticipated and continue for the full flea season.

When the dog is already infested with fleas

PROGRAM does not kill adult fleas. Where adult fleas are already on the dog, it is necessary to treat with a product that is recommended for use against adult fleas. Treatment with PROGRAM Tablets should also be started at this time, and continued for the full flea season.

The flea population in the home will subsequently decline as PROGRAM takes effect.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Wash hands after use.

10. EXPIRY DATE

EXP end {month/year}

11. SPECIAL STORAGE CONDITIONS

Storage

Store in a dry place. Protect from light. Keep container in outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of empty packaging and any remaining product in the household refuse.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only

AVM-GSL

UK authorised veterinary medicinal product.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom
Tel: 01256 353131

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4020

17. MANUFACTURER'S BATCH NUMBER

Batch-No. {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

NATURE/TYPE: Blister Foil

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Program vet. tabl.
Lufenuron. 409,8 mg

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco

3. EXPIRY DATE

{month/year}
Do not use after the stated expiry date

4. BATCH NUMBER

{number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.
For oral use

B. PACKAGE LEAFLET

**PACKAGE LEAFLET:
Program Tablets for dogs**

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

Tel: 01256 353131

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Program Tablets for dogs

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Presentation

Round, biconvex tablets with three different colours and imprinted codes.

Red tablets contain: 67.8 mg lufenuron CGV (side 1) FMF (side 2)

Grey tablets contain: 204.9 mg lufenuron CGV (side 1) GBG (side 2)

White tablets contain: 409.8 mg lufenuron CGV (side 1) DDD (side 2)

Each tablet size is available in blister packs containing six tablets.

4. INDICATION(S)

Uses

For the prevention and long term control of flea infestation, in dogs. PROGRAM is effective against the dominant flea species *Ctenocephalides felis* and *C. canis*. PROGRAM tablets can be administered to all dogs including pregnant bitches and weaned puppies of at least 2.3 kg bodyweight.

5. CONTRAINDICATIONS

Contra-Indications

None. The product is compatible with other flea control products.

6. ADVERSE REACTIONS

On very rare occasions, nervous signs, itching, vomiting or diarrhoea have been reported in dogs following treatment with PROGRAM Tablets.

7. TARGET SPECIES

Dogs

For animal treatment only.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage & Administration

The minimum recommended dose rate is 10 mg per kg bodyweight each month.

Recommended monthly dose:

Dog weight	Red tablets (67.8 mg)	Grey tablets (204.9 mg)	White tablets (409.8 mg)
2.3 kg to 6.7 kg	1 tablet		
6.8 kg to 13.5 kg	2 tablets	OR 1 tablet	
13.6 kg to 20 kg		1 tablet	
21 kg to 40 kg			1 tablet
41 kg to 80 kg			2 tablets

In order to avoid under-dosing in growing puppies, they should be weighed each month prior to dosing.

For oral use only.

If signs of flea infestation or disease persist or appear, consult your veterinary surgeon.

9. ADVICE ON CORRECT ADMINISTRATION

Administration:

To be fully effective the tablets **must** be administered together with food, e.g. added to a portion of the daily food, hidden in pieces of meat, etc or administered by mouth after feeding. After administration, the dog should be watched for several minutes to ensure that the whole dose has been swallowed.

To prevent flea infestations PROGRAM should be administered at monthly intervals for at least six months during the flea season, starting two months before fleas become active. PROGRAM does not kill adult fleas. The product works by preventing the development of flea larvae. If the dog is already infested with fleas, no viable flea eggs are produced from 24 hours after the first administration. The speed of elimination of a pre-existing infestation is dependent upon the number of flea larvae and pupae in the environment when treatment starts and the climatic conditions. If dogs have a high level of flea infestation at the start of the treatment, it is necessary to apply a product that is recommended for use against adult fleas during the first one to two months, or longer depending on the environmental challenge.

It is essential that all dogs and all cats (except unweaned puppies and kittens) living in a household are treated with PROGRAM to stop flea reproduction.

For cats, use PROGRAM suspension.

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Pharmaceutical precautions

Keep out of the reach of children.

Store in a dry place. Protect from light. Keep container in outer carton.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Warnings

Use only in weaned puppies weighing at least 2.3 kg bodyweight.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Wash hands after use.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of empty packaging and any remaining product in the household refuse.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2020

15. OTHER INFORMATION

Legal category:

Package quantities

Blister packs of six tablets and three tablets. Not all pack sizes may be marketed.

Further information

Fleas on unweaned puppies and those weighing less than 2.3 kg can be removed by careful use of a flea comb.

PROGRAM contains lufenuron, a benzoylurea derivative.

After administering PROGRAM orally to the dog, the active ingredient is quickly absorbed. Sufficient absorption is only achieved if administered on a full stomach.

The low excretion rate assures an effective concentration of the active ingredient in the blood for one month.

Fleas take up the active ingredient through the blood and transfer it to their eggs. The formation of larval chitin structures, a process typical to insects, is blocked and the development of their numerous offspring is stopped. A new infestation of the home with fleas is prevented.

Fleas picked up by the dog outside the home environment are prevented from causing a new infestation of the home.

Marketing Authorisation numbers:

Vm 00879/4018 PROGRAM tablets 67.8 mg

Vm 00879/4019 PROGRAM tablets 204.9 mg

Vm 00879/4020 PROGRAM tablets 409.8 mg

Approved 16 October 2020

