

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 Oral Suspension for Small Cats and Kittens 133mg

2. STATEMENT OF ACTIVE SUBSTANCES

lufenuron

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

Net contents: 6 ampoules, each dispenses 1.9 g suspension containing 133 mg lufenuron

5. TARGET SPECIES

Cats between 0.5 kg and 4.5 kg bodyweight

6. INDICATION(S)

Monthly oral treatment for the prevention and long term control of fleas, in small cats and kittens.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Please read the label and package insert completely before use

Administer one ampoule monthly for at least 6 months.

Directions for use

It is essential that all cats and dogs in the household (except unweaned kittens or puppies) are treated with PROGRAM. For dogs use PROGRAM Tablets. PROGRAM Suspension 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.

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

Before fleas are seen on the cat

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

When the cat is already infested with fleas

PROGRAM does not kill adult fleas. Where adult fleas are already on the cat, it is necessary to treat with a product that is recommended for use against adult fleas.

Treatment with PROGRAM Suspension 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

User Warnings

Avoid contact with skin and eyes. If contact occurs wash the affected area with clean water immediately. Seek medical attention if irritation persists. Wash hands after use.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Storage

Do not store above 25°C.

Shake the ampoule prior to opening. 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.,
Lilly House, Priestly Road,
Basingstoke, Hampshire,
RG24 9NL, UK.
Tel: 01256 353131

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4021

17. MANUFACTURER'S BATCH NUMBER

Batch-No.: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

NATURE/TYPE: Foil Laminate Sachet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Program Oral Suspension for Small Cats and Kittens 133mg
Suspension for cats up to 4,5 kg

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One ampoule of PROGRAM SUSPENSION for cats contains
Active substances: Lufenuron 133 mg
Excipients as required to 1,9 g

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 sachet with 6 ampoules

4. ROUTE(S) OF ADMINISTRATION

Administer orally (via the mouth). The recommended minimum dosage is 30 mg active substance per kg of body weight per month.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

BATCH-NR: {number}

7. EXPIRY DATE

EXP: {month/year}
Do not use after the stated expiry date.
Keep container in outer carton.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

NATURE/TYPE: Ampoule

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

2. NAME OF THE MARKETING AUTHORISATION HOLDER

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

MNF{number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Program Oral Suspension for Small Cats and Kittens 133mg
Program Oral Suspension for Large Cats 266mg

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., Lilly House,
Priestly Road, Basingstoke,
Hampshire, RG24 9NL,
UK. Tel: 01256 353131

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Program Oral Suspension for Small Cats and Kittens 133mg
Program Oral Suspension for Large Cats 266mg

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

Presentation

White oral suspension containing 7% w/w lufenuron.

For small cats and kittens:

Package contains six ampoules wrapped in foil laminate sachet. One ampoule dispenses 1.9 g of suspension containing 133 mg of the active ingredient lufenuron.

For large cats:

Package contains six ampoules wrapped in foil laminate sachet. One ampoule dispenses 3.8 g of suspension containing 266 mg of the active ingredient lufenuron.

4. INDICATION(S)

Uses

For the prevention and long term control of flea infestation, in cats. PROGRAM is effective against the dominant flea species *Ctenocephalides felis* and *C. canis*. PROGRAM suspension can be administered to all cats including pregnant and nursing cats and weaned kittens weighing at least 0.5 kg bodyweight.

5. CONTRAINDICATIONS

Contra-Indications

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

6. ADVERSE REACTIONS

In very rare occasions, malaise, itching, vomiting or diarrhoea have been reported in cats following treatment with PROGRAM Suspension.

7. TARGET SPECIES

Cats

For animal treatment only.

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

Dosage & Administration

For oral use only. Shake the ampoule prior to opening.

The minimum recommended dose rate is 30 mg lufenuron/kg/month.

This is achieved by giving:

Cats and kittens between 0.5 kg and 4.5 kg: content of 1 ampoule of PROGRAM 133 mg Oral Suspension for Small Cats and Kittens per month.

Cats over 4.5 kg: content of 1 ampoule of PROGRAM 266 mg Oral Suspension for Large Cats per month. To ensure accurate dosing, cats should be weighed before treatment.

9. ADVICE ON CORRECT ADMINISTRATION

Administration:

To be fully effective the suspension **must** be administered together with food.

Shake the ampoule before use.

The suspension should be added into approximately half of the food ration. The rest of the food should be presented when all the dose has been eaten. If several cats are treated, ensure that each cat is fed individually. The product can also be administered by squeezing the suspension from the ampoule onto the back of the cat's tongue after feeding. To open the ampoule first hold the base tab (which has writing on it) and flick the pack. Then twist off the top portion and squeeze the ampoule several times to administer the suspension. To prevent flea infestations PROGRAM should be administered at monthly intervals for at least six months throughout the flea season, starting two months before fleas become active. If the cat is already infested with fleas, no viable flea eggs are produced from 24 hours after the first administration. The speed of elimination of the infestation is dependent upon the number of flea larvae and pupae in the environment when treatment starts and the climatic conditions.

Program does not kill adult fleas. The product works by preventing the development of flea larvae. If cats have a high level of flea infestation at the start of the treatment, it is necessary to apply a product that is recommended for the use against adult fleas during the first one to two months, or longer depending on the environmental challenge.

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

For dogs, use PROGRAM tablets.

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

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Pharmaceutical precautions

Keep out of reach and sight of children.

Do not store above 25°C.

Keep container in outer carton.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Use only in weaned kittens weighing at least 0.5 kg bodyweight.

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

AVOID CONTACT WITH SKIN AND EYES. IF CONTACT OCCURS, WASH THE AFFECTED AREA WITH CLEAN WATER IMMEDIATELY. SEEK MEDICAL ATTENTION IF IRRITATION PERSISTS. 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

15. OTHER INFORMATION

Legal category: AVM-GSL

Further information

Fleas on unweaned kittens and those weighing less than 0.5 kg can be removed by careful use of flea comb.

PROGRAM contains lufenuron, a benzoylurea derivative.

After administering PROGRAM orally to the cat, 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 cat outside the home environment are prevented from causing a new infestation of the home.

Marketing Authorisation numbers:

Vm 00879/4021 = PROGRAM 133 mg Oral Suspension for small cats and kittens.

Vm 00879/4022 = PROGRAM 266 mg Oral Suspension for large cats.

Approved: 07/06/2017

