ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

PRE-FILLED STERILE, DISPOSABLE GLASS SYRINGES IN A CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Program 80 mg Suspension for Injection
Lufenuron

2. STATEMENT OF ACTIVE SUBSTANCES

Lufenuron 80 mg

3. PHARMACEUTICAL FORM

Suspension for Injection

4. PACKAGE SIZE

10 pre-filled syringes. Each dispenses 0.8 ml of suspension containing 80 mg lufenuron.

5. TARGET SPECIES

Cats equal to or greater than 4 kg bodyweight.

6. INDICATION(S)

For the six month, long-term prevention and control of flea infestations and the treatment of flea allergic dermatitis in cats. The product is effective against the pre-adult stages of the dominant flea species, *Ctenocephalides felis* and *C. canis.*

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For subcutaneous use only.
Shake well before use.
The syringe must only be used once.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

If cats have a flea infestation at the start of treatment, the use of a flea adulticide is recommended. It is essential that all cats (except for unweaned kittens) living in a household are treated with the product to stop flea infestation. Dogs in the same household should be treated as recommended by the prescribing veterinary surgeon.

Read the package leaflet before use.

10. EXPIRY DATE

<EXP {month/year}>

11. SPECIAL STORAGE CONDITIONS

Do not freeze.
Keep the syringes in the outer carton.

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

Disposal: read package leaflet.

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

For animal treatment only. To be supplied only on veterinary prescription.

POM-V

UK authorised veterinary medical product.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach 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

16. MARKETING AUTHORISATION NUMBER

Vm 00879/4038

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

NATURE/TYPE: Syringe Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Program 80 mg Suspension for Injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Lufenuron 80 mg

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

4. ROUTE(S) OF ADMINISTRATION

For subcutaneous injection

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

<Batch> <Lot> <BN> {number}

7. EXPIRY DATE

<EXP {month/year}>

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Program 40 mg Suspension for Injection
Program 80 mg Suspension for Injection

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

Manufacturer responsible for batch release:
Elanco France S.A.S
26 Rue de la Chapelle
68330 Huningue
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Program 40 mg Suspension for Injection
Program 80 mg Suspension for Injection
Lufenuron

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

White to yellow suspension in a pre-filled single-dose syringe for injection.

For cats less than 4 kg bodyweight and weaned kittens
One syringe dispenses 0.4 ml of injectable suspension containing 40 mg of the active substance lufenuron (PROGRAM 40 mg Suspension for Injection).
For cats greater than or equal to 4 kg bodyweight
One syringe dispenses 0.8 ml of injectable suspension containing 80 mg of the active substance lufenuron (PROGRAM 80 mg Suspension for Injection).

4. INDICATION(S)

For the 6 month, long-term prevention and control of flea infestations and the treatment of flea allergic dermatitis in cats. The product is effective against the pre-adult stages of the dominant flea species *Ctenocephalides felis* and *Ctenocephalides canis*.

5. CONTRAINDICATIONS

Do not use in dogs. The excipient Polyvinylpyrrolidone (Povidone) is a potent histamine releasing substance in dogs. A severe reaction may occur in dogs that is not observed in cats.

6. ADVERSE REACTIONS

Adverse reactions are very rarely reported. On very rare occasions injection with the product may cause pain, oedema or alopecia at the injection site. In particular, a small painless swelling may occur and usually disappears within 6 weeks after administration. In very rare cases lethargy has been reported for a few hours after injection, however it disappears quickly.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats equal to or greater than 4 kg bodyweight.

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

The recommended dose rate is 10 mg lufenuron per kg bodyweight when administered parenterally. This is achieved by giving:
Cats and weaned kittens less than 4 kg – content of 1 syringe dispensing 0.4 ml injectable suspension (PROGRAM 40 mg Suspension for Injection)
Cats equal to or greater than 4 kg – content of 1 syringe dispensing 0.8 ml injectable suspension (PROGRAM 80 mg Suspension for Injection)

9. ADVICE ON CORRECT ADMINISTRATION

The syringe must be shaken vigorously to reconstitute the suspension and then injected immediately.
For the product to be fully effective, the whole contents of the syringe must be injected subcutaneously, e.g. dorsally anterior to the shoulder blades.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not freeze.

Do not use this veterinary medicinal product after the expiry date, which is stated on the syringe and carton.

Keep the syringes in the outer carton.

The syringe must only be used once.

12. SPECIAL WARNING(S)

Special warnings for each target species:
If cats have flea infestation at the start of treatment, the use of a flea adulticide is recommended. It is essential that all cats (except for unweaned kittens) living in a household are treated with the product to stop flea infestation. Dogs in the same household should be treated as recommended by the prescribing veterinary surgeon.

Special precautions for use in animals:
The injection should be carried out under aseptic conditions.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In the case of accidental self-injection, a local reaction may occur. In such circumstances seek medical advice immediately and show the package leaflet or label to the physician.

Avoid contact with skin and eyes. In the event of accidental eye or skin contact, wash/rinse the area with clean running water. Seek medical attention if irritation persists.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose (symptoms, emergency procedures, antidotes):
In a study where the product was administered to cats at 5 times the recommended dose, 3 times at 2 monthly intervals, the only adverse effect observed was transient inflammatory reaction at the injection site.

Incompatibilities:
None known.

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

Medicines should not be disposed of via wastewater. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

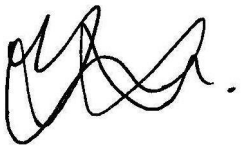
October 2020

15. OTHER INFORMATION

The active substance, lufenuron, is an insect development inhibitor (IDI) belonging to the chemical class of benzoylureas. Lufenuron (INN) is an inhibitor of chitin synthesis and deposition. When administered systemically to the animal, fleas infesting the cat ingest the active substance with their bloodmeal and transfer it to their eggs. As a consequence, the formation of larval chitin structures, a process essential to insects, and the development of viable offspring are blocked. After subcutaneous administration of the product, the active substance is absorbed from a small depot at the site of injection and preferentially sequestered in the adipose tissues, from where it is continuously released metabolically unchanged into the bloodstream. Effective blood levels of lufenuron are attained within 21 days after the initial injection and the low elimination rate assures an effective concentration of the active substance in the bloodstream (above 50-100 ppb) for at least 6 months.
Vm 00879/4037 - Program 40 mg Suspension for Injection
Vm 00879/4038 - Program 80 mg Suspension for Injection

POM-V

To be supplied only on veterinary prescription.



Approved: 22 October 2020