ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Prefilled sterile, disposable glass syringes in a cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PROGRAM 80 mg Suspension for injection for cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Lufenuron 80 mg

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

10 pre-filled sterile 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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD

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 the 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)

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

Keep out of the 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

16. MARKETING AUTHORISATION NUMBER(S)

<MA number>

17. MANUFACTURER'S BATCH NUMBER

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

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Prefilled sterile, disposable glass syringes, individually blistered in a cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PROGRAM 80 mg Suspension for injection for cats.

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

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 80 mg Suspension for injection for cats

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

Manufacturing and responsible for batch release: Solvay Pharmaceuticals B.V., Veerweg 12, 8121 AA OLTS, The Netherlands.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

PROGRAM 80 mg Suspension for injection for cats
Lufenuron

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

One syringe dispenses 0.8 ml of injectable suspension containing 80 mg of the active substance Lufenuron.

Contains the excipient Polyvinylpyrrolidone (Povidone).

4. INDICATION(S)

The product is intended for the prevention of flea multiplication in cats by inhibiting the development of flea eggs to adults for 6 months. The product is effective against eggs and larval stages of fleas. Effective blood levels of Lufenuron are attained within 21 days.

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.
If you notice any serious effects or other effects not mentioned in this leaflet, 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 is 10 mg Lufenuron per kg bodyweight when administered parenterally.
This is achieved by giving:
Cats equal to or greater than 4 kg: content of 1 syringe dispensing 0.8 ml injectable suspension (PROGRAM 80 mg Suspension for injection for cats).

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 content of the syringe must be injected subcutaneously, e.g. dorsally anterior to the shoulder blades.

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.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Do not freeze.

Do not use after the expiry date stated on the syringe and carton.

Keep the syringes in the outer carton.

The syringe must only be used once.

12. SPECIAL WARNING(S)

In a study where the product for cats 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.

The product should be injected under aseptic conditions.

In the case of self-inoculation a local reaction may occur. In such circumstances seek medical advice.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

<MM-YYYY>

<15. OTHER INFORMATION>

Can be used during pregnancy and lactation.
The active ingredient, 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 ~~adsorbed~~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.

<Pack sizes registered>.
Not all pack sizes may be marketed.