SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PROGRAM 40 mg Suspension for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: Lufenuron (INN), 40 mg per syringe (0.4 ml of a 10% suspension)

Excipient: Povidone 12 in an aqueous vehicle.

For the full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Cats and weaned kittens less than 4 kg bodyweight.

4.2 Indications for use, specifying the target species

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

4.3 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.

4.4 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.

4.5 Special precautions for use

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 the 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.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

The **recommended dose** is **10 mg** Lufenuron per kg bodyweight when administered parenterally.

Weight of cats in kg	**less than 4**	Equal to or greater than 4
dose	**1 PROGRAM 40 mg Suspension for Injection Syringe**	1 PROGRAM 80 mg Suspension for Injection Syringe

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.

The syringe must be shaken vigorously to reconstitute the suspension and then injected immediately.

4.10 Overdose (symptoms, emergency procedure, antidotes), if necessary

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 sites.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

The active ingredient, lufenuron, is an insect development inhibitor (IDI) belonging to the chemical class of benzoylureas.

Pharmacotherapeutic group: Antiparasitic products, insecticides and repellents, ectoparasiticides for systemic use, chitin synthesis inhibitors

ATCvet code QP53BC01 (Lufenuron)

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic properties

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 21
Povidone 12
Sodium chloride
Water for injections

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.

The syringe must only be used once.

6.4 Special precautions for storage

Do not freeze.

Keep the syringes in the outer carton.

6.5 Nature and composition of immediate packaging

The product is available as prefilled sterile, disposable 1 ml Hypack SCF glass syringes, containing a withdrawable volume of 0.4 ml of a sterile white to yellow aqueous injectable suspension.

The syringes are ready to use and fitted with a luer-lock and a separable stainless steel needle (gauge 25; 0.5 x 16 mm).

10 individually blistered syringes are packed in a cardboard box.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

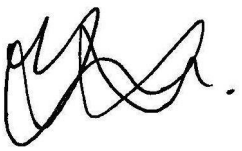
Vm 00879/4037

9. DATE OF FIRST AUTHORISATION

24 December 1997

10. DATE OF REVISION OF THE TEXT

October 2020



Approved: 22 October 2020