SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Program Tablets 204.9 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient	mg/tablet
Lufenuron	204.9000
Excipients	
Ferric Oxide Brown (E172)	0.5613
Titanium dioxide (E171)	2.8067

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Tablet.
Grey, round biconvex tablets

4. CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use

For the prevention and lasting control of flea infestation in dogs. Effective against the dominant flea species *Ctenocephalides felis* and *C. canis*.

4.3 Contra-indications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i) Special precautions for use in animals

Use only in weaned puppies.
If signs of flea infestation or disease persist or appear, consult your veterinary surgeon.

ii) Special precautions to be taken by the person administering the medicinal product to animals

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during pregnancy, lactation or lay

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 minimum recommended dose rate is 10 mg lufenuron per kg body weight per month.

Recommended monthly dose:

Dog weight - 6.8 to 20 kg = 1 tablet

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

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 the product should be administered at monthly intervals for at least six months during the flea season, starting two months before fleas become active.

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 dependant 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 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 to stop flea reproduction.

For cats use Program Suspension.

4.10 Overdose (symptoms, emergency procedures and antidotes) if necessary

Not applicable.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Lufenuron is an insect growth regulator belonging to the benzolyurea group which acts by interfering with the normal synthesis, polymerisation and deposition of chitin.

5.1 Pharmacodynamic properties

ATC vet code: QP53BC01

Fleas take up the active ingredient through the blood and transfer it to their eggs. The formulation 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.

5.2 Pharmacokinetic particulars

After administering 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 ensures an effective concentration of the active ingredient in the blood for one month.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

CORE
Macrogol 8000
Lactose monohydrate
Cellulose Microcrystalline
Pregelatinised starch
Croscarmellose sodium
Magnesium stearate

COATING
Titanium dioxide
Ferric oxide, brown
Hypromellose
Macrogol 8000
Purified talc

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years

6.4 Special precautions for storage

Store in a dry place.
Protect from light.

6.5 Nature and composition of the immediate packaging

Pack size: 6 or 3 tablets.

Container: Clear colourless polyvinyl chloride/low density polyethylene/polyvinyl chloride / aluminium blister pack. Containing grey, round, biconvex tablets.

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste material 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 00879/4019

9. DATE OF FIRST AUTHORISATION

08 July 1993

10. DATE OF REVISION OF THE TEXT

October 2020

Approved 16 October 2020