

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Program Tablets 67.8mg

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

<u>Active ingredient</u>	<u>mg/tablet</u>
Lufenuron	67.8000
<u>Excipients</u>	
Ferric Oxide Red (E172)	0.2806
Titanium dioxide (E171)	0.8420

For a full list of excipients see section 6.1

### **3. PHARMACEUTICAL FORM**

Tablet.  
Red 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 of at least 2.3 kg bodyweight.  
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/ai/kg/month.

Recommended monthly dose:

Dog weight – 2.3 to 6.7 kg = 1 tablet

Dog weight - 6.8 to 13.5 kg = 2 tablets

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 benzoylurea 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 PECULIARS**

### **6.1 List of excipients**

#### **CORE**

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

#### **COATING**

Titanium dioxide  
Ferric oxide, red  
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 red, 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 00879/4018

**9. DATE OF FIRST AUTHORISATION**

08 July 1993

**10. DATE OF REVISION OF THE TEXT**

October 2020

Approved 16 October 2020

