

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Program Oral Suspension for Large Cats 266 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient mg/ampoule

Lufenuron 266

Excipients

Methyl parahydroxybenzoate 4.56

Propyl parahydroxybenzoate 1.14

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM;

Oral suspension

White aqueous suspension

4. CLINICAL PARTICULARS:

4.1 Target Species

Cats greater than 4.5kg bodyweight

4.2 Indications for use

For the prevention and lasting control of flea infestation in cats. 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

None

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

Avoid contact with skin and eyes. If contact occurs wash the affected area with clean water immediately. Seek medical attention if irritation persists. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

On very rare occasions, malaise, itching, vomiting or diarrhoea have been reported in cats following treatment with Program Suspension.

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 30mg a.i./kg/month. This is achieved by giving cats over 4.5kg the contents of 1 ampoule

To be fully effective the suspension **MUST** be administered together with food. Shake the ampoule prior to opening. The suspension should be added to approximately half of the food ration. The rest of the food should be presented when all the dose has been eaten. If several cats are treated, ensure that each cat is fed individually. The product can also be administered by squeezing the suspension directly from the ampoule onto the back of the cat's tongue after feeding.

To open the ampoule first hold the base tab (which has writing on it) and flick the pack. Then twist off the top portion and squeeze the ampoule several times to administer the suspension.

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. To ensure accurate dosing, cats should be weighed before treatment.

If the cat is already infested with fleas, no viable flea eggs are produced from 24 hours after the first administration. The speed of elimination of the pre-existing infestation is dependent upon the number of flea larvae and pupae in the environment when treatment starts and climatic conditions.

Program does not kill adult fleas. The product works by preventing the development of flea larvae. If cats 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 or two months, or longer depending on the environmental challenge.

It is essential that all cats and dogs (except unweaned puppies and kittens) living in a household are treated to stop flea reproduction.

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

Not known

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 formation 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 cat outside the home environment are prevented from causing a new infestation of the home.

5.2 Pharmacokinetic particulars

After administering orally to the cat, 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

Methyl parahydroxybenzoate
Propyl parahydroxybenzoate
Glycerol
Avicel RC 591 (Microcrystalline cellulose with Carmellose Sodium)
Water Purified

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

Do not store above 25°C
Shake the ampoule prior to opening.

6.5 Nature and composition of the immediate packaging

Low density polyethylene ampoules each dispensing 3.8g suspension. Six or three ampoules are packed in a sealed aluminium foil sachet.
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
Lilly House
Priestley Road
Basingstoke
Hampshire
RG24 9NL

8 MARKETING AUTHORISATION NUMBER

Vm 00879/4022

9 DATE OF FIRST AUTHORISATION

16th May 1995

10 DATE OF REVISION OF THE TEXT

January 2016

Approved: 13 January 2016

