**IRISH MEDICINES BOARD ACT 1995**

**ANIMAL REMEDIES REGULATIONS, 2005**

**(S.I. No. 734 of 2005)**

VPA: **10835/024/002**
Case No: 7001566

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 734 of 2005) hereby grants to:

**Novartis Animal Health**

**Industrial Park**, **Cork Road**, **Waterford**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

**Program Tablets 204.9mg**

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

Signed on behalf of the Irish Medicines Board this

_____

A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

# Part II

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Program Tablets, 204.9 mg

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains**:**

| Active Substance | |
|---|---|
| Lufenuron | 204.9 mg |
| **Excipients** | |
| Titanium dioxide PH (E171) | 2.8 mg |
| Iron Oxide brown 17278 (E172) | 0.5 mg |

For a full list of excipients see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet.

Dark grey violet, round slightly biconvex film coated tablets embossed on one side ‘CGV’ and ‘FMF’ on the other.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Dogs.

### 4.2 Indications for use, specifying the target species

For the prevention of flea infestation on dogs.

Susceptible flea species: *Ctencephalides canis*, *Ctencephalides felis*.

### 4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

### 4.4 Special warnings for each target species

None.

## 4.5 Special precautions for use

**Special precautions for use in animals**

None.

**Special precautions to be taken by the person administering the veterinary medicinal product to animals**

None.

## 4.6 Adverse reactions (frequency and seriousness)

None known.

## 4.7 Use during pregnancy, lactation or lay

Program tablets can be administered to all dogs including pregnant bitches and puppies taking solid food.

## 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 rate is 10mg Lufenuron per kg bodyweight/month.
The following table can be used as a guide.

| | |
|---|---|
| 2.3 kg to 6.7kg | 1 red tablet |
| 6.7 kg to 20kg | 1 grey tablet |
| 20 kg to 40kg | 1 violet-white tablet |

Above 40kg treat according to bodyweight.

For oral administration.

The tablets should be administered together with food e.g. mixed into 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 Program should be administered at monthly intervals for at least 6 months during the flea season, starting at least 2 months before fleas become active. In areas where fleas are active all year Program should be given continuously at monthly intervals.

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

If dogs have a high level of flea infestation at the start of the treatment, it may be necessary to apply a flea adulticide during the first 1 - 2 months.

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

Not applicable.

## 4.11 Withdrawal Period(s)

Not applicable.

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

| Active principle: | Pharmacotherapeutic group: | ATCvet Code |
|---|---|---|
| Lufenuron | Insect Growth Regulator | QP53BC01 |

## 5.1 Pharmacodynamic properties

Lufenuron belongs to the chemical group of benzoylureas, and is an IGR (Insect Growth Regulator) or IDI (Insect Development Inhibitor). It inhibits the development of fleas by interfering with the normal synthesis, polymerisation and deposition of chitin, the principal component of the arthropod exoskeleton. The adult flea absorbs lufenuron via its bloodmeal. At therapeutic levels, lufenuron has no effect on adult fleas, but passes transovarially to act on eggs and larvae, thus interrupting the insect life cycle.

## 5.2 Pharmacokinetic properties

Following oral administration, lufenuron is distributed via the blood within a median of 2 hours (2 – 48 h) to the adipose tissue, from which, metabolically unmodified, it is constantly released above the minimum effective concentration for at least one month (half life between 15 and 50 days).

## 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Macrogol
Lactose
Microcrystalline Cellulose
Cornstarch
Carmellose Sodium
Magnesium Stearate

Coating

Hydroxypropylcellulose
Macrogol
Talc
Titanium Dioxide
Iron oxide brown

## 6.2 Incompatibilities

None known.

## 6.3 Shelf-life

The shelf life expiry date for this product shall not exceed 5 years from the date of manufacture.

## 6.4 Special precautions for storage

Do not store above 25$^{o}$C.

## 6.5 Nature and composition of immediate packaging

6 tablets blistered in aluminium foil and packed in a cardboard carton.

## 6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

## 7 MARKETING AUTHORISATION HOLDER

Novartis Animal Health Ireland Ltd
Industrial Park
Cork Road
Waterford

## 8 MARKETING AUTHORISATION NUMBER(S)

VPA 10835/24/2

## 9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20 June 2004