SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PYRIPROXYFEN 0.01g/g PREMIX FOR DOG VIRBAC.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 g premix contains:

Active substance
Pyriproxyfen……0.01 g

For the full list of excipients, see point 6.1

3. PHARMACEUTICAL FORM

Premix for medicated feed
Light, brown homogeneous powder.

4. CLINICAL PARTICULARS

4.1. Target species

Dogs

4.2. Indications for use, specifying the target species

In dogs:
Prevention of flea multiplication by sterilising the eggs.

4.3. Contraindications

None known.

4.4. Special warnings for each target species

If there are several dogs in a same home, the treatment should be administered to all of them.
All animals in the home should be treated with a suitable flea control preparation (i.e. with an appropriate insecticidal product), at the same time that the product is administered to the dogs. If there are occasional flea re-infestations during treatment, adult fleas should be also eliminated with appropriate insecticidal products.

4.5. Special precautions for use

i) Special precautions for use in animals

This medicinal premix is intended for the manufacturing of solid medicinal foods and cannot be used as it is.

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

None

iii) Other precautions

4.6. Adverse reactions (frequency and seriousness)

None known.

4.7. Use during pregnancy, lactation or lay

Studies in laboratory animals (rat, mouse, rabbit) did not reveal any teratogenic or embryotoxic effects attributable to pyriproxyfen. The safety of this medicinal food in nursing and pregnant bitches has been demonstrated at three times the minimal recommended dose. The use of the product in nursing and pregnant bitches is therefore possible.

4.8. Interaction with other medicinal products and other forms of interaction

None known

4.9. Amount(s) to be administered and administration route

For incorporation into dry feed at the registered mill.

Minimal recommended dose: 500 µg of pyriproxyfen per kg bodyweight per day.
The mixing rate of the medicinal premix with the solid food cannot be lower than 2.7 kg/tonne.

A manufacturer who is approved to incorporate directly at any concentration, veterinary medicinal products or premixtures containing such products must be responsible for mixing when incorporation is less than 2 kg per tonne for final feed.

The food ration should be distributed once per day and adjusted by the veterinarian to ensure the recommended dosage. The food ration can be consumed over the day. The amount of food consumed depends on body weight of the animal, its physiological state and the metabolizable energy of the feed.

In general, the first administration in the year should take place just before the assumed first flea infestation period. The treatment should be carried on until the usual infestation period ends according to the recommendation of the veterinarian.

If the administration is temporarily stopped (for a maximum of 2 days, e.g. for the week-end, the holidays or temporary appetite reduction, etc.), the dog remains protected.

The maximum recommended dose is 3 times the minimal one

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

No undesirable effect has been shown when the product is administered at doses up to 10 times the recommended dose
Up to a dose of 5283 µg/kg body weight per day (i.e. approximately 10 times the minimal recommended dose) administered for 28 days, no adverse effects were observed.

4.11. Withdrawal period(s)

Not applicable

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: ectoparasiticide for systemic use
ATC Vet code: QP53RX

5.1. Pharmacodynamic properties

Pyriproxyfen is an insect growth inhibitor which imitates the juvenile hormone. It stops eggs and larvae developing and prevents the appearance of new adult fleas. It acts by absorption by adult fleas, sterilising the eggs during their maturation before being laid

5.2. Pharmacokinetic particulars

The product is for oral use only after mixing into feed.
Pyriproxyfen is absorbed via the intestinal tract in sufficient quantity to exert a systemic activity on mature adult female fleas. This activity takes place within an hour following the dog's first meal.
After the first oral administration of the product at a dose of 500 µg/kg of Pyriproxyfen, C_{max} of 21.5 ± 4.0 ng/ml was obtained at 4.0 ± 1.3 hours post-dose and the 24h-AUC (between two administrations) was 145.2 ± 34.0 ng.h/mL.
Mean elimination half-life of Pyriproxyfen was 10.0 ± 3.4 hours. Absolute bioavailability was 49 ± 10 %.

No significant difference was observed when comparing pharmacokinetic parameters obtained after the first and the sixth days of administration. Therefore, no accumulation of pyriproxyfen in plasma is expected after 6 days treatment of medicated feed.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Propylene glycol dicaprylate/dicaprate
Wholemeal wheat (as support)

6.2. Incompatibilities

None known.

6.3. Shelf-life

Shelf life of the medicated premix as packaged for sale 15 months.
Shelf life of the medicated premix after opening the bag: use immediately
Shelf life of the medicated premix after incorporation in the feed: 15 months
Shelf life of the medicated feed after first opening of the bags:

For the medium & large dog:

- 3 kg bag: maximum 15 days
- 12 kg bag: maximum 2 months

For the toy & small dog:

- 3 kg bag: maximum 1 month
- 7 kg bag: maximum 2 months

6.4. Special precautions for storage

The medicated premix does not require any special storage conditions.
Store the medicated feed below 30°C.
Keep the container in the outer carton.

6.5. Nature and composition of immediate packaging

Low density polyethylene bag

Box of 1.5 kg bag
Box of 22.5 kg bag
Barrel of 1.5 kg bag
Barrel of 22.5 kg bag

Not all pack sizes may be marketed

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

This product should not be discharged into water courses as this may be dangerous for fish and other aquatic organisms.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Virbac
1ère avenue - 2065m - LID
06516 Carros
France

8. MARKETING AUTHORISATION NUMBER

05653/4125

9. DATE OF FIRST AUTHORISATION

10 June 2005

10. DATE OF REVISION OF THE TEXT

January 2018

Approved: 24 January 2018