PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX or BARREL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PYRIPROXYFEN 1g/g PREMIX FOR DOG VIRBAC.
Pyriproxyfen

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1g premix contains:

Active substance:
Pyriproxyfen……0.01 g/g

3. PHARMACEUTICAL FORM

Premix for medicated feed
Light, brown homogeneous powder

4. PACKAGE SIZE

1.5 kg
22.5 kg

5. TARGET SPECIES

Dogs

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened: use immediately.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

05653/4125

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – COMBINED LABEL AND PACKAGE LEAFLET

BAG

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
Virbac
1ère avenue - 2065m - LID
06516 Carros
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

PYRIPROXYFEN 1g/g PREMIX FOR DOG VIRBAC.
Pyriproxyfen

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT

Each 1 g premix contains:

Active substance:
Pyriproxyfen……0.01 g/g

Propylene glycol dicaprylate/dicaprate
Wholemeal wheat (as support)

4. INDICATION(S)

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

5. CONTRAINDICATIONS

None known.

6. ADVERSE REACTIONS

None known.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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 kg/tonne.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD(S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the bag after EXP.

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

The expiry date refers to the last day of that month

12. SPECIAL WARNING(S)

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.

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
None

Pregnancy and lactation and 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.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose (symptoms, emergency procedures, antidotes):
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 for 28 days, no adverse effects were observed.

Incompatibilities:
None known.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

<15. OTHER INFORMATION>

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.

Approved: 24 January 2018