

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

HDPE Bottles

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:

QUIMICA DE MUNGUÍA S.A.
Derio Bidea, 51
48100 Munguía- Vizcaya
SPAIN

2. Name of the veterinary medicinal product

Dixie Ornamental Birds 0.75 mg/ml cutaneous spray solution
Fipronil

3. Statement of the active substance (s) and other ingredients

Each ml contains:

Active substance:
Fipronil 0.75 mg

A clear, colourless solution.

4. Pharmaceutical form

Cutaneous spray, solution.

5. Package size

125 ml
250 ml
500 ml
1000 ml

6. Indication(s)

Treatment of mite's infestations by *Dermanyssus gallinae* in ornamental birds. In canaries, one application provided insecticidal efficacy up to 21 days: The test item showed 74.1% efficacy 16/17 days after treatment and 99.2% after 21 days.

7. Contraindications

Do not use in birds which are intended to produce meat or eggs for human consumption. Do not use on sick or convalescent animals.

Do not use in rabbits, as adverse reactions and even death could occur.

Do not apply on wounds or damaged skin.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

8. Adverse reactions

None known.

In canaries no adverse events were observed at the therapeutic dose. No safety data has been sent in ornamental birds other than canaries, so it is recommendable to follow-up the animal after been treated.

<The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).>

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

9. Target species

Ornamental birds

10. Dosage for each species, route(s) and method of administration

Cutaneous use.

Method of administration –

Adjust the pump nozzle to spray setting. Spray the veterinary medicinal product on the back of the bird from a distance of approximately - 5-10 cm

Dose:

To ensure the correct dose, and to avoid underdosing and overdosing, the bodyweight(s) of the bird(s) to be treated should be determined as accurately as possible.

Apply a dose of 10 mg fipronil /kg bw (7.5 mg - 15 mg bw).

This dose corresponds to:

- Small Birds (Canary, parakeets, and similar) 1 to 2 pulsations of 0.30 ml for the 125 and 250ml spray
- Big Birds (parrots, doves and similar) 1 to 5 pulsations of 0.75 ml for 500 ml, and 1000 ml spray

In absence of safety studies, in particular data on the margin safety, if the infestation persists, the minimum interval for repeating the treatment must be 21 days.

11. Advice on correct administration

Do not use Dixie Ornamental Birds 0.75 mg/ml cutaneous spray solution if you notice description of the visible signs of deterioration.

12. Withdrawal period(s)

Not applicable. Do not use in birds which are intended to produce meat and eggs for human consumption.

13. Special storage precautions
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This veterinary medicinal product does not require any special storage conditions

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle after EXP: The expiry date refers to the last day of that month.

14. Special warning(s)

Special precautions for use in animals:

For external use only.

Avoid contact with the animal's eyes.

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

People with a known hypersensitivity to fipronil or any of the excipients should avoid contact with the veterinary medicinal product.

This product can cause mucous membrane and eye irritation. Therefore, contact of the product with mouth and eyes should be avoided. In case of accidental ocular exposure or irritation of the eyes during administration, these should be rinsed immediately and thoroughly with plain water. If eye irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.

Avoid content coming into contact with the fingers. The use of PVC or nitrile gloves is recommended.

Dispose of gloves after use and then wash hands with soap and water. In case of dermal exposure, wash immediately with soap and water. If irritation occurs, seek medical advice. Do not breathe spray. People with known sensitivity or asthma may be particularly sensitive to the product. Do not use product if you have previously experienced a reaction to it. Spray animals in a well ventilated room.

Do not apply in the presence of children.

Wash hands after use.

Do not smoke, drink or eat during the application.

Treated animals should not be handled until the feathers are dry, and children should not be allowed to play with treated animals until the feathers are dry.

Fertility and lay:

.Laboratory studies did not reveal any teratogenic effect of fipronil in the rat and rabbit. Data is not available from specific studies in breeding birds or during the lay. The safety of the veterinary medicinal product has not been established, therefore do not use in birds in lay or in breeding birds.

Interaction with other medicinal products and other forms of interaction:

Do not use simultaneously with other mite products which are applied directly onto the animal.

Overdose (symptoms, emergency procedures, antidotes):

No information on overdose is currently available in the target species.

Incompatibilities:

Not applicable

15. Special precautions for the disposal of unused product or waste materials, if any

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

The veterinary medicinal product should not enter water courses as this may be dangerous for fish and other aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

16. Date on which the label was last approved

17. Other information>

Package sizes:

Bottle of 125 ml with mechanical dosing pump of 0.30 ml/pulsation

Bottle of 250 ml with mechanical dosing pump of 0.30 ml/pulsation

Bottle of 500 ml with mechanical dosing pump of 0.75 ml/pulsation

Bottle of 1000 ml with mechanical dosing pump of 0.75 ml/pulsation

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the marketing authorisation holder.

18. The words “For animal treatment only” and conditions or restrictions regarding supply and use, if applicable

For animal treatment only.

19. The words “Keep out of the sight and reach of children”
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Keep out of the sight and reach of children.

20. Expiry date

EXP {month/year}

Shelf life after first opening the container: 1 year

Once opened use by ..

21. Marketing authorisation number(s)
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22. Manufacturer's batch number
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Batch{number}