

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dixie Ornamental Birds 0.75 mg/ml cutaneous spray solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Fipronil 0.75 mg

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cutaneous spray, solution.

A clear, colourless solution

4. CLINICAL PARTICULARS

4.1 Target species

Ornamental birds

4.2 Indications for use, specifying the target species

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.

4.3 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.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

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 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.

4.6 Adverse reactions (frequency and seriousness)

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).>

4.7 Use during pregnancy, lactation or 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.

4.8 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.

4.9 Amounts to be administered and administration route

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 of safety, if the infestation persists, the minimum interval for repeating the treatment must be 21 days.

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

No information on overdose is currently available in the target species (see section 4.6).

4.11 Withdrawal period(s)

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, including insecticides

ATC vet code: QP53AX15

5.1 Pharmacodynamic properties

Fipronil is an insecticide/acaricide belonging to the phenylpyrazole family active against *Dermanyssus gallinae*. It acts by inhibiting the GABA-gate channels (GABA_A receptor antagonist) and disturbs normal neuronal influx by targeting the GABA-gate channel and thereby blocking pre- and post-synaptic transfer of chloride ions across the membrane. This results in uncontrolled activity of the central nervous system and death in insects and acarids.

5.2 Pharmacokinetic particulars

After a local application of fipronil, it is slightly absorbed through the skin of rats, dogs and cats. Pharmacokinetic studies in rats suggest that fipronil excretes mainly in the faeces (45–75%) and little in the urine (5–25%). In all species fipronil is mainly metabolised to its sulphone derivative (RM 1602), which also possesses insecticidal and acaricidal properties.

It is known that fipronil has a good bioavailability if ingested. This should be taken into account mainly when given the VMP to ornamental birds, as toxicity – related effects cannot be discarded due to differences in body metabolism capacity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Povidone

Isopropanol

Water purified

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

Shelf life after first opening the immediate packaging: 1 year.

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

High Density Polyethylene (HDPE) white opaque bottles equipped with mechanical dosing pumps of HDPE/LDPE that is screwed onto the top of the bottle and protected by a polypropylene cap.

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.

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

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.

7. MARKETING AUTHORISATION HOLDER

QUIMICA DE MUNGUÍA S.A.

Derio Bidea, 51

48100 Munguía- Vizcaya
SPAIN

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<Date of first authorisation:

<Date of last renewal:

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Dispensing conditions: Veterinary medicinal product not subject to prescription