

SUMMARY OF THE PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's 4 Fleas Protector 60 mg Spot-On Solution for Cats and Kittens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

For one pipette containing 0.6 ml of solution:

- active substance

pyriproxyfen 60 mg

Excipients:

Butylhydroxytoluene..... 0.6 mg

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution.

Clear solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the target species

Prevention of flea multiplication (adult and larval stages of *Ctenocephalides felis* sensitive to pyriproxyfen) in cats by inhibiting egg development for 3 months.

4.3 Contra-indications

Do not use in kittens weighing less than 1 kg.

Do not use if your cat is unwell or recovering from an illness.

4.4 Special warnings for each target species

Fleas should be removed from lactating females and young kittens by careful use of a flea comb.

In case several animals are part of the same household, appropriate treatment should be carried out for each animal. As for any parasitocidal product, its frequent

and repeated use may cause the development of parasite resistance to the active ingredient.

Infestations occurring during the initial administration or appearing during the treatment period may be eliminated with appropriate medicinal insecticides.

The influence of bathing or wetting immediately after treatment has not been evaluated. Therefore, it is likely that the efficacy will be reduced if the animal is wetted or shampooed immediately after the treatment.

4.5 Special precautions for use

(i) Special precautions for use in animals

For external use only.

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

Avoid contact with skin and eyes. In case of accidental contact, rinse abundantly with water.

In case of eye irritation, seek medical attention.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Among the rare suspected adverse reactions, transient cutaneous reactions on the application site (squamosis, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use. Exceptionally, hypersalivation or vomiting have been observed after treatment.

4.7 Use during pregnancy, lactation or lay

Studies performed in laboratory animals (rats, mice, rabbits) did not show any teratogenic or embryotoxic effects of pyriproxyfen at therapeutic doses.

It is not recommended to use Johnson's 4 Fleas Protector 60 mg for Cats and Kittens on pregnant or lactating queens.

4.8 Interaction with other medicinal products and other forms of interaction

From clinical field studies, no interaction was observed between organophosphate or pyrethroid compounds and pyriproxyfen.

4.9 Amounts to be administered and administration route

Single administration of one pipette per cat (equivalent to a minimal dosage of 10 mg per kg of bodyweight). This dosage may be achieved by applying one pipette of 0.6 ml for a cat weighing between 1 kg and 6 kg.

Johnson's 4 Fleas Protector 60 mg for Cats and Kittens should be administered directly on the skin of the animal, at the base of the neck. Care should be taken to

maintain contact between the pipette and skin during the administration of the product. Apply the contents by carefully squeezing the bottom of the tube 4 times.

A second application can be made 3 months after the first one to prolong efficacy for a further 3 months.

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

Studies have shown the absence of undesirable effects at doses up to 3 times the recommended dose daily for three consecutive days.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: other antiparasiticides for topical use.
ATCvet code: QP53AX23.

5.1 Pharmacodynamic properties

Pyriproxyfen is an inhibitor of flea growth, which has the ability to mimic the juvenile hormone. The molecule prevents, by contact, the emergence of adult insects by blocking the development of eggs (ovicidal effect) and larvae (larvicidal effect), which are subsequently eliminated.

Following contact and/or ingestion by adult fleas, the molecule also acts by sterilising eggs during their maturation and before being laid.

5.2 Pharmacokinetic properties

Pyriproxyfen is distributed over the coat of the treated animal in sufficient amount to induce, within 24 hours after the administration of the product, a sterilising activity on both the eggs and female adult fleas.

After administration of the recommended dosage to cats between the shoulder blades, pyriproxyfen is rapidly distributed over the coat within 24 hours with substantial levels appearing in the fur at the base of the tail. Simultaneously, maximum concentrations of 10000 µg/g and 230 µg/g are measured respectively near the site of application and in the middle region (back and flanks). Pyriproxyfen remains in the fur with detectable levels lasting at least 84 days post-treatment. With regards to plasmatic concentration, the percutaneous absorption of pyriproxyfen is low with an absolute bioavailability of 25 % over the 3-month period of time after application of the product. The pyriproxyfen plasma peak is reached after 3 to 8 h with 24 ng/ml. The elimination half-life of pyriproxyfen in plasma occurs in 32 days.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Butylhydroxytoluene
- Diethylene glycol monoethyl ether.

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and composition of immediate packaging

Polypropylene pipettes and closure containing 0.6 ml of solution.

Presentations:

- box containing 1 pipette
- box on blister card containing one pipette.

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

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

The product should not enter watercourses as this may be dangerous for fish and other aquatic organisms.

7. MARKETING-AUTHORISATION HOLDER

Alfamed S.A.S. - 13^{ème} rue - L.I.D. - 06517 Carros Cedex - France

8. MARKETING-AUTHORISATION NUMBER

Vm 17902/4012

9. DATE OF FIRST AUTHORISATION

20 September 2007

10. DATE OF REVISION OF THE TEXT

July 2012