SUMMARY OF THE PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's 4 Fleas Protector 30 mg Spot-On Solution for Medium Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

For one pipette containing 1.5 ml of solution:
- active substance
pyriproxyfen.....30 mg

Excipients:

Butylhdroxytoluene.....0.27 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

Dogs.

4.2 Indications for use, specifying the target species

Prevention of flea multiplication (adult and larval stages of *Ctenocephalides felis* sensitive to pyriproxyfen*)* in dogs weighing over 6 kg up to 15 kg by inhibiting egg development for 3 months.

4.3 Contra-indications

Do not use in puppies less than 1 month of age.
Do not use if your dog is unwell or recovering from an illness.

4.4 Special warnings for each target species

Fleas should be removed from lactating females and young puppies 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 parasiticidal 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, the efficacy may be reduced if the animal is wetted or shampooed up to 3 days 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.

(iii) Other precautions

Prevent dogs from swimming in ponds and waterways for up to three days after the treatment.

4.6 Adverse reactions (frequency and seriousness)

Among the very rare suspected adverse reactions, transient cutaneous reactions such as pruritus, erythema have been observed after use in dogs.

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.
The safety of the product in pregnant or nursing bitches has been demonstrated. The use of Johnson’s 4 Fleas Protector 30 mg for Medium Dogs in pregnant or nursing bitches is possible.

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 dog (equivalent to a minimal dosage of 2 mg per kg of bodyweight). This dosage may be achieved by applying one pipette of 1.5 ml for a dog weighing over 6 kg up to 15 kg.

Johnson's 4 Fleas Protector 30 mg for Medium Dogs 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 ectoparasiticides 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 dogs 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 800 µg/g and 66 µg/g are measured respectively near

the application site and in the middle region (back and flanks). Pyriproxyfen remains in the fur with detectable levels lasting at least 42 days post-treatment.
With regards to plasmatic concentration, the percutaneous absorption of pyriproxyfen is low with an absolute bioavailability of 37 % over the 3-month period of time after application of the product. The pyriproxyfen plasma peak is reached after 1 to 3 days with 2.8 ng/ml. The elimination half-life of pyriproxyfen in plasma occurs in 6 days.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Butylhydroxyanisole
- 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 1.5 ml of solution.

Presentations:
- box containing 1 pipette
- box on blister card containing 1 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. – 13ème rue – L.I.D. – 06517 Carros Cedex – France

8. MARKETING-AUTHORISATION NUMBER

Vm 17902/4011

9. DATE OF FIRST AUTHORISATION

20 September 2007

10. DATE OF REVISION OF THE TEXT

July 2012