SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's 4Fleas 57mg Tablets for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains:

Active substance:
Nitenpyram 57.0 mg

Excipients:
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.

White to light yellow, round, biconvex tablets, with bevelled edges, imprinted on one side with "HIH", on the other side with "CG".

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

Treatment of flea infestations (*C. felis*) on dogs.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i) Special precautions for use in animals

Do not use on dogs weighing less than 11 kg.

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

None.

4.6 Adverse reactions (frequency and seriousness)

For the first hour after administration, the pet may scratch more than normal. This effect is caused by the fleas reacting to the product. In very rare cases this may present as transient signs of hyperactivity, panting, vocalisation, and excessive grooming/licking. Transient neurological signs such as muscle tremors, ataxia and convulsions have also been reported in very rare occasions.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Nitenpyram can be used during pregnancy and lactation. Studies in laboratory animals (rats and rabbits) have produced no evidence of teratogenic or foetotoxic effects and the safety of the product was demonstrated in pregnant and lactating cats and dogs.

4.8 Interaction with other medicinal products and other forms of interaction

None known. No adverse drug reactions were seen in clinical studies when nitenpyram was administered with other veterinary medicinal products including commonly used flea products, anthelmintics, vaccines or antibiotics.

4.9 Amounts to be administered and administration route

The minimum effective recommended dose is 1 mg/kg, with the following recommendations:

One Johnson’s 4Fleas 57 mg tablet should be given to dogs weighing 11.1 kg to 57.0 kg and two tablets for dogs weighing over 57 kg when a flea infestation is detected. The frequency of treatment depends on the degree of infestation. In the case of a severe flea infestation, it may be necessary to treat the animals every day or every other day, until the flea infestation is controlled. Treatment may be resumed if fleas reappear. No more than one treatment should be given per day.

Tablets should be given orally, with or without food. In order to improve palatability, tablets can be disguised in a small quantity of food immediately prior to administration.

Johnson’s 4Fleas tablets do not have persistent activity. To prevent re-infestation, a suitable treatment to control immature stages of the flea life cycle is recommended. The veterinary surgeon should establish an appropriate treatment regime.

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

Nitenpyram is well-tolerated by the target species. Overdoses up to 50 mg/kg in cats and up to 70 mg/kg in dogs were asymptomatic.

Side-effects such as salivation, vomiting, soft stools, seizures, or decreased activity are observed at higher dosages and their seriousness increases as dosages increase. Symptoms disappear quickly and recovery is complete by 24 hours after overdosing because of the rapid elimination of nitenpyram. During 6 months of daily dosing in cats and dogs no clinically significant treatment-related side effects were observed.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other ectoparasiticides for systemic use,
ATCvet code: QP53B X02.

5.1. Pharmacodynamic properties

The active ingredient, nitenpyram belongs to the chemical class of neonicotinoids which bind and inhibit insect specific nicotinic acetylcholine receptors. Nitenpyram interferes with nerve transmission and leads to the death of adult fleas. Nitenpyram does not inhibit acetylcholinesterase.

Effects on fleas (*Ctenocephalides felis*) may be seen as soon as 15-30 minutes after administration of the product to the host animal. This coincides with the first blood meal taken by fleas after sufficient blood levels are reached. Between 95% and 100% efficacy is observed within the first 6 hours and 100% efficacy is reached within 24 hours with no residual activity.

5.2 Pharmacokinetic particulars

Nitenpyram is rapidly and to over 90% absorbed from the gastrointestinal tract of cats and dogs. Feeding does not affect absorption in dogs. Feeding slightly delays T_{max} in cats without affecting the other pharmacokinetic properties and without affecting efficacy. The maximum blood concentration is reached after 0.5 to 2 hours in both

fasted target species and the elimination half-life is about 4 hours in dogs and 8 hours in cats. More than 90% is eliminated in the urine within 1 day in dogs and 2 days in cats, mainly as the unchanged molecule.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cellulose Microcrystalline
Maize starch
Lactose monohydrate

Silica colloidal anhydrous
Magnesium stearate

6.2 Incompatibilities

None known.

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Cardboard box with 1 or 10 polyamide/aluminium/PVC-aluminium blisters. Each blister contains 6 tablets.

Cardboard box with 1 polyamide/aluminium/PVC-aluminium blister. Each blister contains 3 tablets.

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

8. MARKETING AUTHORISATION NUMBER

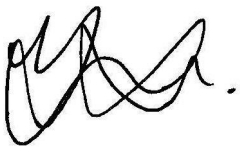
Vm 00879/4062

9. DATE OF FIRST AUTHORISATION

12 November 2003

10. DATE OF REVISION OF THE TEXT

October 2020



Approved: 22 October 2020