SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's 4fleas 40 mg Spot-on Solution for Dogs Less than 4 kg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.4 ml pipette contains:

Active substance:

Imidacloprid	40 mg

Excipients:

Butylhydroxytoluene (E 321)	0.4 mg
Benzyl alcohol (E1519)	332.8 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution
Clear yellow to slightly brownish solution

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

For the prevention and treatment of flea infestations and for the treatment of biting lice (*Trichodectes canis*) on dogs of less than 4 kg body weight.

Fleas are killed within one day following treatment. One treatment prevents further flea infestation for four weeks.

4.3 Contraindications

Do not treat unweaned puppies of less than 8 weeks of age.
Do not use in animals that are known to be hypersensitive to the active substance or any of the excipients.

4.4 Special warnings

Re-infestation from emergence of new fleas in the environment may continue to occur for six weeks or longer after treatment is initiated. More than one treatment may therefore be required, depending on the level of fleas in the environment. To aid reduction in environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developing stages is recommended. In order to reduce further the environmental challenge, it is recommended that all dogs, cats and rabbits in the household are treated with a suitable product.

If there are several pets in the household, it is advisable to treat all pets at the same time. Fleas can be detected by parting pet's coat and examining skin for signs of flea activity or by combing coat with a fine-toothed flea comb. Frequent scratching or excessive grooming can also be signs of flea infestation. Fleas from pets often infest pet's basket, bedding and regular resting areas, such as carpets and soft furnishings which should be vacuumed regularly and treated periodically with an insecticide suitable for household use, preferably containing an I.G.R. (Insect Growth Regulator) to control flea egg development and help break the flea life cycle. Wash and change pet bedding regularly.

The product remains effective if the animal becomes wet, for example after swimming or exposure to heavy rain. However, in cases of frequent swimming or bathing re-treatment may become necessary, depending on the presence of fleas in the environment. In these cases do not treat more frequently than once weekly.

In case of biting louse infestation, the animal should be re-examined 30 days after treatment as some animals may require a second treatment.

If signs of disease persist or appear, consult a veterinary surgeon

4.5 Special precautions for use

i. Special precautions for use in animals

This product is for topical use and should not be administered orally.
Care should be taken to avoid the contents of the pipette coming into contact with the eyes or mouth of the recipient animal.
Do not allow recently treated animals to groom each other.
Apply only to undamaged skin.

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

People with known skin sensitivity to imidacloprid or benzyl alcohol may be particularly sensitive to this product and should avoid contact with the veterinary medicinal product.

This product contains benzyl alcohol and may cause skin sensitisation or transient skin reactions in rare cases (for example, irritation, tingling).

Avoid contact of the product with the eyes or mouth. Do not eat, drink or smoke during application.
Wash off any skin contamination with soap and water.

After application, do not stroke or groom pets until application site is dry.

It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals are not allowed to sleep with owners, especially children.

If the product gets into eyes accidentally, the eyes should be thoroughly rinsed with clean water. If skin or eye irritation persists, or the product is accidentally swallowed, obtain medical attention, showing the package leaflet or carton to the physician.
Wash hands thoroughly after use.

In order to prevent children from getting access to pipettes, keep the pipette in the original packaging until ready for use and dispose of used pipettes immediately.

iii. Other precautions

Imidacloprid is toxic to aquatic organisms. To avoid adverse effects on aquatic organisms, treated dogs should not be allowed to enter water courses for 48 hours after treatment.

Keep treated pets away from materials such as leather, soft furnishings, plastics, etc until site of application is completely dry as contact may damage these surfaces.

4.6 Adverse reactions (frequency and seriousness)

The product is bitter tasting and salivation may occasionally occur if the animal licks the application site immediately after treatment. This is not a sign of intoxication and disappears within some minutes without treatment (see also section 4.9 *Amounts to be administered and administration route*).
In very rare occasions skin reactions such as hair loss, redness, itching and skin lesions may occur. Agitation, disorientation and, in exceptional cases, excessive salivation and nervous signs such as incoordination, tremors and depression have been reported.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions 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

No primary embryotoxic, teratogenic or reproductive toxic effects have been observed during the studies with imidacloprid on rats and rabbits. Studies on pregnant and lactating bitches together with their offspring are limited. Evidence so far suggests that no adverse effects are to be expected in these animals.

Consult your veterinary surgeon before using in pregnant or nursing animals

4.8 Interaction with other medicinal products and other forms of interaction

No incompatibility has been observed between this product at twice the recommended dose and the following commonly used veterinary products: fenthion, lufenuron, milbemycin, febantel, pyrantel and praziquantel. The compatibility of the product was also demonstrated with a wide range of routine treatments under field conditions including vaccination.

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

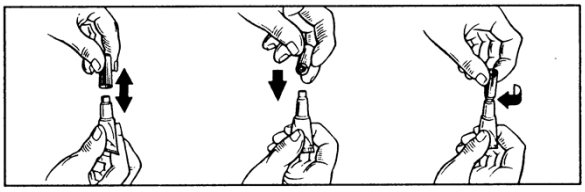
4.9 Amounts to be administered and administration route

Dosage and Treatment Schedule

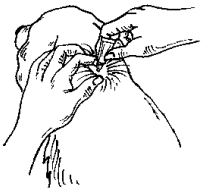
Product	Dog (kg bw)	Number of Pipettes	Imidacloprid (mg/kg bw)
Johnson's 4fleas 40 mg Spot-on solution for dogs less than 4 kg	< 4 kg	1 x 0.4 ml	minimum of 10
Dogs weighing ≥ 4kg bodyweight: use the appropriate Johnson's 4fleas Spot-on solution for dogs [UK] / Advantage Flea Control Spot-on solution for dogs [IE] product			

Method of Administration

Remove one pipette from the package. Hold pipette in an upright position, twist and pull off cap. Use reversed cap to twist and remove seal from pipette.



With the dog in the standing position, part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.



Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.
The product is bitter tasting and salivation may occasionally occur if the dog licks the application site immediately after treatment. This is not a sign of intoxication and disappears within some minutes without treatment. Correct application will minimize the opportunity for the dog to lick the product.
Apply only to undamaged skin.

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

No adverse clinical signs were produced by either individual doses of up to 200 mg/kg body weight (five to eight times the therapeutic dose), daily treatments at 100 mg/kg body weight for five consecutive days or weekly treatments at five times the maximum dose rate for eight consecutive weeks.

In rare cases of overdose or licking of treated fur, nervous system disorders (such as twitching, tremors, ataxia, mydriasis, miosis, lethargy) can occur. Poisoning following inadvertent oral uptake in animals is unlikely. In this event, treatment should be symptomatic under veterinary medical attention. There is no known specific antidote but administration of activated charcoal may be beneficial.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use; Imidacloprid
ATCvet code: QP53AX17

5.1 Pharmacodynamic properties

Imidacloprid, 1-(6-Chloro-3-pyridylmethyl)-N-nitro-imidazolidin-2-ylideneamine is an ectoparasiticide belonging to a group of chloronicotinyl compounds. Chemically, it is more accurately described as a chloronicotinyl nitroguanidine.

The substance has a high affinity for the nicotinergic acetylcholine receptors in the post-synaptic region of the central nervous system (CNS). The ensuing inhibition of cholinergic transmission in insects results in paralysis and death. Due to the weak nature of the interaction with mammalian nicotinergic receptor sites and the postulated poor penetration through the blood/brain barrier in mammals, it has virtually no effect on the mammalian CNS. The minimal

pharmacological activity in mammals is supported by safety studies involving systemic administration of sub-lethal doses to rabbits, mice and rats.

In further studies, in addition to the adulticide flea efficacy of imidacloprid, a larvicidal flea efficacy in the surroundings of the treated pet has been demonstrated. Larval stages in the pet's surroundings are killed following contact with a treated animal.

5.2 Pharmacokinetic particulars

The product is indicated for cutaneous administration. Following topical application in dogs, the solution is quickly distributed over the animal. Acute dermal studies in the rat and target animal overdose and serum kinetic studies have established that systemic absorption is very low, transient and not relevant for the clinical efficacy. This has been further demonstrated by a study in which fleas were not killed after having fed on previously treated animals once the animal's skin and fur had been cleaned of all active material.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxytoluene E321
Benzyl alcohol E1519
Propylene carbonate

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years

6.4 Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions.
Keep the blister in the outer carton.

6.5 Nature and composition of immediate packaging

Pack sizes 0.4 ml solution per pipette
Blister pack containing 1, 2, 3, 4, or 6 unit dose pipettes

Container White polypropylene pipettes with caps

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

Imidacloprid may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers. 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 00879/4142

9. DATE OF FIRST AUTHORISATION

06 May 2014

10. DATE OF REVISION OF THE TEXT

October 2020

Approved 02 October 2020