SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frento Flea Control 400 mg spot-on solution for extra-large dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pipette of 4.0 ml contains:

Active substance:
Imidacloprid 400.0 mg

Excipient(s):
Butylhydroxytoluene (E 321) 4.0 mg
Benzyl alcohol (E 1519) 3328.0 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 use on dogs from 25 kg to less than 40 kg body weight.
For the prevention and treatment of flea infestation.
For the treatment of biting lice (*Trichodectes canis*) where this has been previously diagnosed by a veterinary surgeon.
Fleas are killed within one day following treatment. One treatment prevents further flea infestation for four weeks. The product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD) where this has been previously diagnosed by a veterinary surgeon.

4.3 Contraindications

Do not treat puppies of less than 8 weeks of age.
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

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.

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 re-treat more frequently than once weekly.

In case of biting louse infestation, a further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

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.
Apply only to undamaged skin.
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.

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

This product contains benzyl alcohol and may cause skin sensitisation or transient skin reactions in rare cases (for example, irritation, tingling).
People with known hypersensitivity to imidacloprid should avoid contact with the veterinary medicinal product.
Avoid contact between the product and skin, eyes or mouth.
Do not eat, drink or smoke during application.
Do not massage the application site.
After application, do not stroke or groom animals until application site is dry.
Wash off any skin contamination with soap and water.
Wash hands thoroughly after use.
If the product gets into eyes accidentally, the eyes should be thoroughly flushed with water.
If skin or eye irritation persists, obtain medical attention.
If the product is accidentally swallowed, obtain medical attention 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 surface water for 48 hours after treatment.

The solvent in this product may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

4.6 Adverse reactions (frequency and seriousness)

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.
In very rare occasions skin reactions such as hair loss, redness, itching and skin lesions may occur. Agitation and disorientation has also been reported. 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 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

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.

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

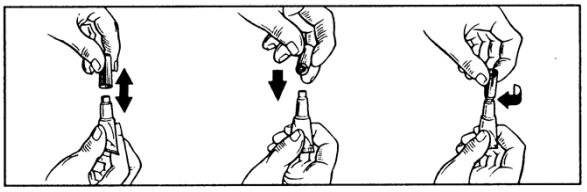
This product is for topical use and should not be administered orally. Animals should be weighed accurately prior to treatment.

Dosage and Treatment Schedule

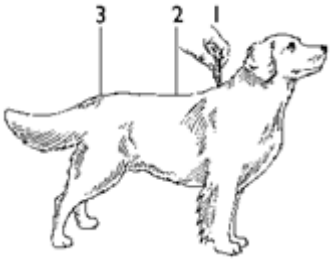
Dog (kg bw)	Product	Number of Pipettes	Imidacloprid (mg/kg bw)
≥ 25 < 40 kg	Frento Flea Control 400 mg spot-on solution for extra-large dogs	1 x 4.0 ml	minimum of 10
For dogs less than 25 kg bodyweight the appropriate *Frento Flea Control spot-on solution for dogs* product should be used For dogs ≥40 kg bodyweight an appropriate combination of pipettes should be used.			

Method of Administration

Remove one pipette from the package. For dogs of 40 kg body weight and greater use two pipettes. Hold pipette in an upright position, twist and pull off cap. Use reversed cap to twist and remove seal from pipette.



The dog should be standing for easy application. The entire contents of the pipette(s) should be applied evenly to three or four spots all located at different application sites along the dog's backline from the shoulder to the base of the tail. At each spot part the coat until the skin is visible. Place the tip of the pipette on the skin and gently squeeze to expel a portion of 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(s)

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 ecto-parasiticide belonging to a group of chloronicotinyl compounds. Chemically, it is more a

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

* CAS-No. 138261-41-3

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 (E 321)
Benzyl alcohol (E 1519)
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 storage conditions.
Keep the blister in the outer carton.

6.5 Nature and composition of immediate packaging

Fill volume:	4.0 ml
Type of the container:	White polypropylene pipettes with caps
Material of the secondary packaging:	PVC/Al blister packs in a cardboard box.
Package sizes:	Blister packs containing either 2, 3, 4, or 6 unit dose pipettes or a single unit dose pipette without blister. 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.
Imidacloprid may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

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 00879/4139

9. DATE OF FIRST AUTHORISATION

03 July 2018

10. DATE OF REVISION OF THE TEXT

October 2020

Approved: 21 October 2020