LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Outer carton, pack size of 1, 2, 3, 4 and 6 pipettes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each 4.0 ml pipette contains:
Active substance: 400 mg imidacloprid

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

1 pipette (1x 4.0 ml)
2 pipettes (2x 4.0 ml)
3 pipettes (3x 4.0 ml)
4 pipettes (4x 4.0 ml)
6 pipettes (6x 4.0 ml)

5. TARGET SPECIES

Dogs

6. INDICATION(S)

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.

[Pictograms]


Flea


Louse

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external use only.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
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.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Keep the blister in the outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS; IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
[Prescription status to be completed nationally; Blue Box]

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

Manufactured by
KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Str. 324, 24106 Kiel
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4139

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Pipette label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frento Flea Control

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Imidacloprid(e) 400 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4.0 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

[Dog-Pictogram]

≥ 25 kg < 40 kg

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frento Flea Control for extra-large dogs
Imidacloprid

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco logo.

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

[Dog-Pictogram]

≥ 25 kg < 40 kg

4.0 ml

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Frento Flea Control spot-on solution for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

Manufacturer responsible for batch release
KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Str. 324, 24106 Kiel
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

UK:
Frento Flea Control 40 mg spot-on solution for small dogs
Frento Flea Control 100 mg spot-on solution for medium dogs
Frento Flea Control 250 mg spot-on solution for large dogs
Frento Flea Control 400 mg spot-on solution for extra-large dogs

Imidacloprid

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each pipette of clear yellow to slightly brownish solution contains:

	0.4 ml	**1.0 ml**	**2.5 ml**	**4.0 ml**
Active substance				
Imidacloprid	40 mg	100 mg	250 mg	400 mg
Excipients:				
Butylhydroxytoluene (E321)	0.4 mg	1.0 mg	2.5 mg	4.0 mg
Benzyl alcohol (E 1519)	332.8 mg	832.0 mg	2080.0 mg	3328.0 mg

4. INDICATION(S)

For the prevention and treatment of flea infestation on dogs.
For the treatment of biting lice (*Trichodectes canis*) on dogs 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.

5. 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.

6. ADVERSE REACTIONS

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 exceptionally in dogs.

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).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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

Any instructions given by a veterinary surgeon for the use of this product should be followed.

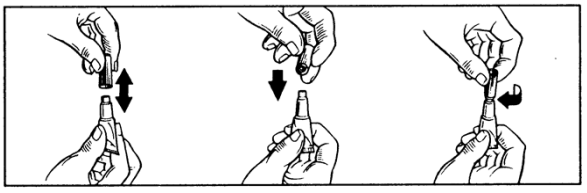
Dosage and Treatment Schedule

Dog (kg bw)	Product	Number of Pipettes	Imidaclopri d (mg/kg bw)
Less than 4 kg	Frento Flea Control for small dogs	1 x 0.4 ml	minimum of 10
4 to less than 10 kg	Frento Flea Control for medium dogs	1 x 1.0 ml	minimum of 10
10 to less than 25 kg	Frento Flea Control for large dogs	1 x 2.5 ml	minimum of 10
25 to less than 40 kg	Frento Flea Control for extra-large dogs	1 x 4.0 ml	minimum of 10
40 kg and greater	An appropriate combination of pipettes should be used.		

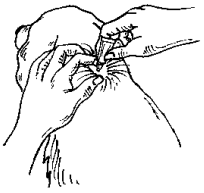
In case of biting louse infestation, a further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

Method of Administration

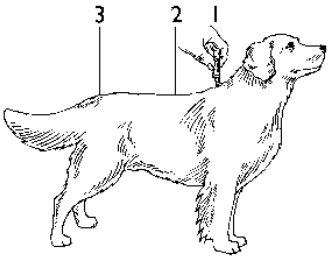
Remove one pipette from the package. For dogs of 40 kg body weight and greater use two pipettes (an appropriate combination of pipettes based on body weight). Hold pipette in an upright position, twist and pull off cap. Use reversed cap to twist and remove seal from pipette.



<u>For dogs less than 25 kg body weight:</u>
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.



For dogs of 25 kg body weight and greater:
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.

9. ADVICE ON CORRECT ADMINISTRATION

For external use only.
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.
Correct application will minimize the opportunity for the dog to lick the product, please also refer to section *Adverse Reactions*.
Apply only to undamaged skin. Do not allow recently treated animals to groom each other.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the blister in the outer carton.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton, blister and pipette after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

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 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.

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.

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.

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.

Pregnancy and lactation:

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.

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.

Overdose (symptoms, emergency procedures, antidotes):
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.

Incompatibilities:
None known.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

[to be adapted nationally, if required]
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2020

15. OTHER INFORMATION

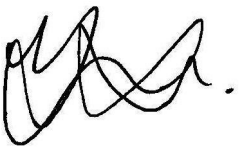
Pack sizes 0.4 / 1.0 / 2.5 / 4.0 ml solution per pipette

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.

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.

[Further information like prescription status or marketing authorisation numbers to be completed nationally, if required]



Approved: 21 October 2020