

## **SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Frento Forte Flohschutztropfen 400 mg Lösung zum Auftropfen für sehr große Hunde [AT]

## 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

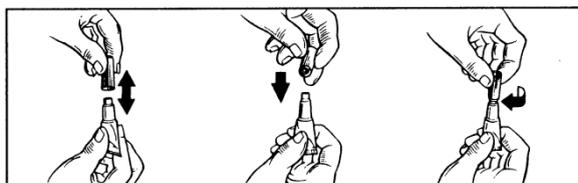
This product is for topical use and should not be administered orally. Animals should be weighed accurately prior to treatment.

##### *Dosage and Treatment Schedule*

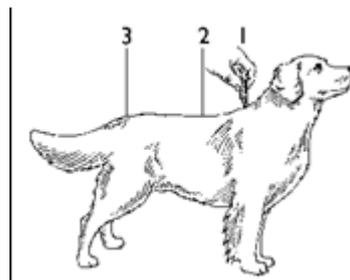
Dog (kg bw)	Product	Number of Pipettes	Imidacloprid (mg/kg bw)
≥ 25 < 40 kg	Frento Flea Control / Frento Forte 400 mg spot-on solution for extra-large dogs	1 x 4.0 ml	minimum of 10
For dogs less than 25 kg bodyweight the appropriate <i>Frento Flea Control / Frento Forte spot-on solution for dogs</i> 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 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 nicotinic 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 nicotinic 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

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\* CAS-No. 138261-41-3

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 (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**

*[to be completed nationally]*

**8. MARKETING AUTHORISATION NUMBER(S)**

*[to be completed nationally]*

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

*[to be completed in accordance with national requirements after conclusion of the MR phase]*

**10. DATE OF REVISION OF THE TEXT**

*[to be completed in accordance with national requirements after conclusion of the MR phase]*

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.

**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 [UK]

Frento Forte Flohschutztropfen 400 mg Lösung zum Auftropfen für sehr große Hunde [AT]

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**

*[to be completed nationally]*

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

**16. MARKETING AUTHORISATION NUMBER(S)**

*[to be completed nationally]*

**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 [UK]  
Frento Forte [AT]

**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 [UK]  
Frento Forte für sehr große Hunde [AT]  
Imidacloprid

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**



**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 / Frento Forte 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  
*[to be completed nationally]*

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

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

UK:	AT:
Frento Flea Control 40 mg spot-on solution for small dogs	Frento Forte Flohschutztropfen 40 mg Lösung zum Auftropfen für kleine Hunde
Frento Flea Control 100 mg spot-on solution for medium dogs	Frento Forte Flohschutztropfen 100 mg Lösung zum Auftropfen für mittelgroße Hunde
Frento Flea Control 250 mg spot-on solution for large dogs	Frento Forte Flohschutztropfen 250 mg Lösung zum Auftropfen für große Hunde
Frento Flea Control 400 mg spot-on solution for extra-large dogs	Frento Forte Flohschutztropfen 400 mg Lösung zum Auftropfen für sehr große Hunde

Imidacloprid

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

Each pipette of clear yellow to slightly brownish solution contains:

	<b>0.4 ml</b>	<b>1.0 ml</b>	<b>2.5 ml</b>	<b>4.0 ml</b>
<b>Active substance</b>				
Imidacloprid	40 mg	100 mg	250 mg	400 mg
<b>Excipients:</b>				
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.

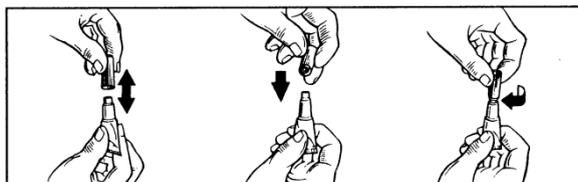
### *Dosage and Treatment Schedule*

<b>Dog (kg bw)</b>	<b>Product</b>	<b>Number of Pipettes</b>	<b>Imidacloprid (mg/kg bw)</b>
Less than 4 kg	Frento Flea Control / Frento Forte for small dogs	1 x 0.4 ml	minimum of 10
4 to less than 10 kg	Frento Flea Control / Frento Forte for medium dogs	1 x 1.0 ml	minimum of 10
10 to less than 25 kg	Frento Flea Control / Frento Forte for large dogs	1 x 2.5 ml	minimum of 10
25 to less than 40 kg	Frento Flea Control / Frento Forte 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.

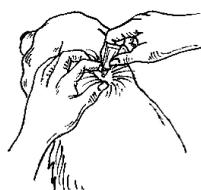
### *Method of Administration*

Remove one pipette from the package. For dogs of 40 kg body weight and greater use two pipettes (4.0 ml pipette). Hold pipette in an upright position, twist and pull off cap. Use reversed cap to twist and remove seal from pipette.



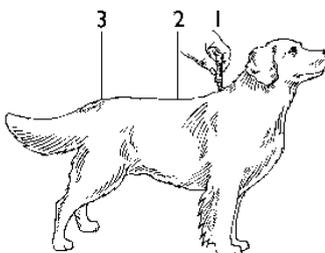
For dogs less than 25 kg body weight:

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**

**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]*