[Version 9.1, 11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frento Forte 40 mg spot-on solution for cats (<4 kg) [AT]
Advantage 40 mg spot-on solution for cats (<4 kg) [DK, IE, IT, NL, UK(NI)]
Medicalpet 40 mg spot-on solution for cats (<4 kg) [ES]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.4 ml unit dose (pipette) contains:

Active substance:
Imidacloprid 40 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E1519)	832.0 mg/ml
Butylhydroxytoluene (E321)	1.0 mg/ml
Propylene carbonate	

Clear yellow to slightly brownish solution.

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each target species

For the prevention and treatment of flea infestations on cats.
One treatment prevents further flea infestation for three to four weeks.
The veterinary medicinal 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.

3.3 Contraindications

Do not treat unweaned kittens of less than 8 weeks of age.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal.

The possibility that other animals in the same household can be a source of re-infection with fleas should be considered, and these should be treated as necessary with an appropriate product.

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, especially of the animal's basket, bedding and regular resting areas such as carpets and soft furnishings. In order to reduce further the environmental challenge, it is recommended that all cats in the household are treated. Treatment of nursing queens controls flea infestations on both dam and offspring.

The veterinary medicinal product remains effective if the animal becomes wet, for example after exposure to heavy rain. However, 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

This veterinary medicinal 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.

Any collar should be removed prior to application of the veterinary medicinal product. Prior to re-fitting the collar, the treated area should be visually assessed to ensure it is dry.

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

This veterinary medicinal 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 and benzyl alcohol should avoid contact with the veterinary medicinal product.
Avoid contact between the veterinary medicinal product and skin, eyes, or mouth.
Do not massage the application site.
Do not eat, drink, or smoke during application.
Wash off any skin contamination with soap and water.
If the veterinary medicinal product gets into eyes accidentally, the eyes should be thoroughly flushed with water. If skin or eye irritation persists, or the veterinary medicinal product is accidentally swallowed, seek medical advice immediately and show the package leaflet or the label to the physician.
After application, do not stroke or groom animals until application site is dry.
Wash hands thoroughly after use.

Special precautions for the protection of the environment:

Imidacloprid is toxic to aquatic organisms, see section 5.5.

Other precautions:

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

3.6 Adverse events

Cats:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Agitation Diarrhoea[1], Hypersalivation[2], Vomiting[1] Neurological signs (e.g. Depression, Incoordination, Tremor) Application site reaction (e.g. Hair loss, Itching, Reddening of the skin, Skin lesion)

[1]May occur after oral ingestion.
[2]May occur if the cat licks the application site immediately after treatment due to the bitter taste. This is not a sign of intoxication and disappears within some minutes without treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

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

3.8 Interaction with other medicinal products and other forms of interaction

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

3.9 Administration routes and dosage

Spot-on use. For external use only.

Underdosing could result in ineffective use and may favour resistance development.
To ensure a correct dosage, body weight should be determined as accurately as possible.

Dosage and treatment schedule:
The recommended minimum dose is 10 mg imidacloprid per kg body weight (bw), equivalent to 0.1 ml/kg bw of the veterinary medicinal product.

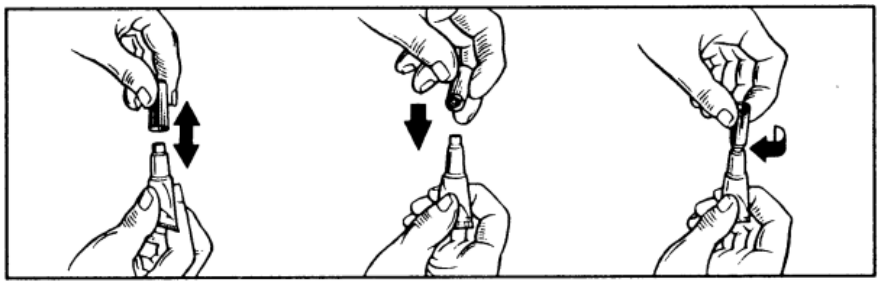
Cat weight (kg)	Pipette size to be used	Pipette volume (ml)	Imidacloprid (mg/kg bw)
<4 kg	Frento Forte 40 mg for cats	0.4	minimum of 10

For cats of 4 kg bw and greater, use the appropriate available pipette size for the weight of the cat to be treated.

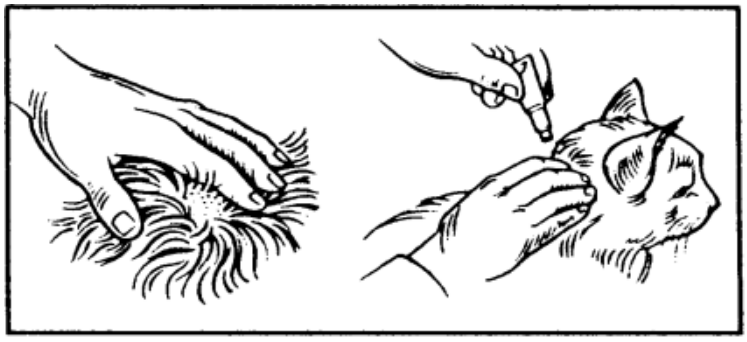
For treatment or prevention of infestations with fleas, the need for and frequency of re-treatment(s) should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

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.



Part the hair on the cat's neck at the base of the skull 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.



Application at the base of the skull will minimize the opportunity for the cat to lick the veterinary medicinal product.

Apply only to undamaged skin.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse clinical signs were produced using doses of five times the therapeutic level weekly 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QP53AX17

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

The veterinary medicinal product is indicated for cutaneous administration. Following topical application in cats, 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

White polypropylene unit dose pipette closed with white polypropylene screw cap.
Unit dose pipettes are packed in polyvinyl chloride and aluminium foil blisters.

Pack sizes: Cardboard box containing a total of 1, 2, 3, 4 or 6 unit dose pipettes in a blister sheet.
Each unit dose pipette contains 0.4 ml of solution.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as imidacloprid may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

{DD month YYYY}

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription. (IE)
Veterinary medicinal product not subject to prescription. (AT, DK, ES, IT, NL, UK(NI))

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frento Forte 40 mg spot-on solution [AT]
Advantage 40 mg spot-on solution [DK, IE, IT, NL, UK(NI)]
Medicalpet 40 mg spot-on solution [ES]

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.4 ml pipette contains: 40 mg imidacloprid

3. PACKAGE SIZE

1 pipette
2 pipettes
3 pipettes
4 pipettes
6 pipettes

4. TARGET SPECIES

<4 kg

5. INDICATIONS

For veterinary medicinal products not subject to veterinary prescription:

Flea prevention and treatment for cats.
One treatment prevents further flea infestation for three to four weeks.
The veterinary medicinal 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.
[Pictogram]

Flea

6. ROUTES OF ADMINISTRATION

Spot-on use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Keep the blister in the outer carton.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco logo

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frento Forte [AT]
Advantage [DK, IE, IT, NL, UK(NI)]
Medicalpet [ES]

<4 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

40 mg imidacloprid

0.4 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PIPETTE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frento Forte [AT]
Advantage [DK, IE, IT, NL, UK(NI)]
Medicalpet [ES]

<4 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

0.4 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Frento Forte 40 mg spot-on solution for cats (<4 kg) [AT]
Advantage 40 mg spot-on solution for cats (<4 kg) [DK, IE, IT, NL, UK(NI)]
Medicalpet 40 mg spot-on solution for cats (<4 kg) [ES]

Frento Forte 80 mg spot-on solution for cats (≥4 kg) [AT]
Advantage 80 mg spot-on solution for cats (≥4 kg) [DK, IE, IT, NL, UK(NI)]
Medicalpet 80 mg spot-on solution for cats (≥4 kg) [ES]

2. Composition

Each unit dose (pipette) contains:

	Unit Dose	Imidacloprid
Frento Forte 40 mg for cats (<4 kg)	0.4 ml	40 mg
Frento Forte 80 mg for cats (≥4 kg)	0.8 ml	80 mg

Excipients:
832.0 mg/ml benzyl alcohol (E1519), 1.0 mg/ml butylhydroxytoluene (E321)

Clear yellow to slightly brownish solution.

3. Target species

Cats.

4. Indications for use

For the prevention and treatment of flea infestations on cats. One treatment prevents further flea infestation for three to four weeks.
The veterinary medicinal 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 unweaned kittens 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. Special warnings

Special warnings:

Unnecessary use of antiparasitics or use deviating from the instructions given in the package leaflet may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the

veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal.

The possibility that other animals in the same household can be a source of re-infection with fleas should be considered, and these should be treated as necessary with an appropriate product.

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, especially of the animal's basket, bedding and regular resting areas such as carpets and soft furnishings. In order to reduce further the environmental challenge, it is recommended that all cats in the household are treated. Treatment of nursing queens controls flea infestations on both dam and offspring.

The veterinary medicinal product remains effective if the animal becomes wet, for example after exposure to heavy rain. However, 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.

Special precautions for safe use in the target species:

This veterinary medicinal 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. Any collar should be removed prior to application of the veterinary medicinal product. Prior to re-fitting the collar, the treated area should be visually assessed to ensure it is dry.

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

This veterinary medicinal 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 and benzyl alcohol should avoid contact with the veterinary medicinal product.
Avoid contact between the veterinary medicinal product and skin, eyes, or mouth.
Do not massage the application site. Do not eat, drink, or smoke during application.
Wash off any skin contamination with soap and water.
If the veterinary medicinal product gets into eyes accidentally, the eyes should be thoroughly flushed with water. If skin or eye irritation persists, or the veterinary medicinal product is accidentally swallowed, seek medical advice immediately and show the package leaflet or the label to the physician
After application, do not stroke or groom animals until application site is dry.
Wash hands thoroughly after use.

Special precautions for the protection of the environment:

Imidacloprid is toxic to aquatic organisms. See also section 'Special precautions for disposal'.

Other precautions:

The solvent in this veterinary medicinal 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 reproductive toxic effects have been observed in rats and no primary embryotoxic or teratogenic toxic effects have been observed during the studies on rats and rabbits. Studies on pregnant and lactating queens 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 veterinary medicinal product at twice the recommended dose and the following commonly used veterinary medicinal products: lufenuron, pyrantel and praziquantel. The compatibility of the veterinary medicinal product was also demonstrated with a wide range of routine treatments under field conditions including vaccination.

Overdose:

No adverse clinical signs were produced using doses of five times the therapeutic level weekly 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.

7. Adverse events

Cats:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):
Agitation (hyperactivity) Diarrhoea[1], Hypersalivation (drooling)[2], Vomiting[1] Neurological signs (e.g. Depression (lethargy), Incoordination, Tremor) Application site reaction (e.g. Hair loss, Itching, Reddening of the skin, Skin lesion)

[1]May occur after oral ingestion.
[2]May occur if the cat licks the application site immediately after treatment due to the bitter taste. This is not a sign of intoxication and disappears within some minutes without treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or its local representative> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Spot-on use. For external use only.

Underdosing could result in ineffective use and may favour resistance development.
To ensure a correct dosage, body weight should be determined as accurately as possible.

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

Dosage and treatment schedule:
The recommended minimum dose is 10 mg imidacloprid per kg body weight (bw), equivalent to 0.1 ml/kg bw of the veterinary medicinal product.

Cat weight (kg)	Pipette size to be used	Pipette volume (ml)	Imidacloprid (mg/kg bw)
<4 kg	Frento Forte 40 mg for cats	0.4	minimum of 10
≥4 kg	Frento Forte 80 mg for cats	0.8	minimum of 10

Select the appropriate pipette size for the weight of the cat to be treated.

For treatment or prevention of infestations with fleas, the need for and frequency of re-treatment(s) should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

9. Advice on correct 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 as shown in figure 1.

Part the hair on the cat's neck at the base of the skull 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 as shown in figure 2.

Application at the base of the skull will minimize the opportunity for the cat to lick the veterinary medicinal product. Apply only to undamaged skin.

For monolingual packaging only:
Figures are shown below.

For multilingual packaging only:
Figures are shown at the end of the leaflet.

In order to facilitate multilingual package leaflets, figures were numbered, and this text added so that graphics can be printed only once at the end of the leaflet for multilingual leaflets.

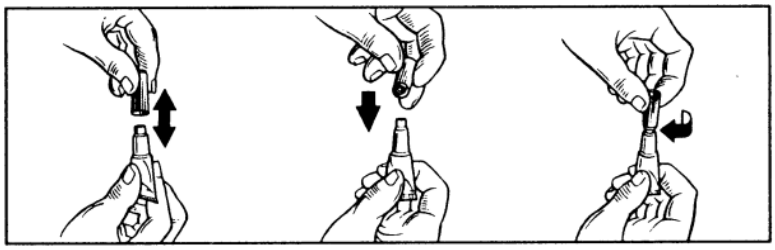


Figure 1

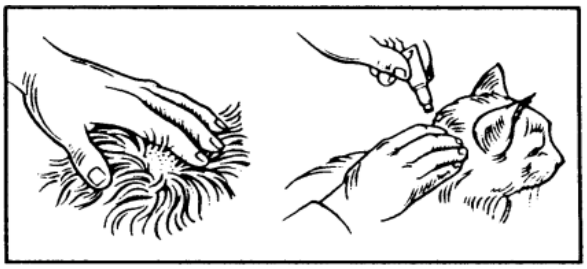


Figure 2

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Keep the blister in the outer carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and pipette after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

This veterinary medicinal product should not enter water courses as imidacloprid may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription. (IE)
Veterinary medicinal product not subject to prescription. (AT, DK, ES, IT, NL, UK(NI))

14. Marketing authorisation numbers and pack sizes

Cardboard box containing a total of 1, 2, 3, 4 or 6 unit dose pipettes in a blister sheet.
Each unit dose pipette contains 0.4 or 0.8 ml of solution.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

16. Contact details

Marketing authorisation holder <and contact details to report suspected adverse events>:

Manufacturer responsible for batch release:

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

Local representatives <and contact details to report suspected adverse events>:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

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.