[Version 9,03/2022]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fleaguard Plus 600 mg/3000 mg Spot-on Solution for Dogs over 40 kg up to 60 kg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 6 ml pipette contains:

Active substances:
Imidacloprid 600 mg
Permethrin 40:60 3000 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butylhydroxytoluene (E321)	6 mg
Citric acid	-
Triglycerides, medium chain	-
N-methylpyrrolidone	-

Clear yellowish to brownish solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs (from 40 kg to 60 kg).

3.2 Indications for use for each target species

For dogs with, or at risk from mixed infestation by fleas, ticks, biting lices, sandflies and mosquitoes targeted by each of the combined active substances.
The veterinary medicinal product is only indicated when use against all the following parasite species is required at the same time.

Treatment of infestation and prevention of re-infestation by flea (*Ctenocephalides canis, Ctenocephalides felis*) due to insecticidal activity for 4 weeks.
Fleas on dogs are killed within one day following treatment. The product can be used as part of a treatment strategy for flea allergy dermatitis (FAD) suitably diagnosed by the responsible veterinarian.

Treatment of infestation by biting lice (*Trichodectes canis*).

The product has persistent acaricidal and repellent (anti-feeding) efficacy against tick infestations (*Rhipicephalus sanguineus* and *Ixodes Ricinus* for four weeks, and *Dermacentor recticulatus* for three weeks).

One treatment provides repellent (anti-feeding) activity against sand flies (*Phlebotomus papatasi* for two weeks and *Phlebotomus pernicious* for three weeks), against mosquitoes (*Aedes aegypti* for two weeks and *Culex pipiens* for four weeks) and against stable flies (*Stomoxys calcitrans*) for four weeks.

Reduction of the risk of transmission of the pathogen *Ehrlichia canis*, thereby reducing the risk of canine ehrlichiosis by acaricidal and repellent activity on the tick vector *Rhipicephalus sanguineus.* The reduction in risk has been shown to begin from 3 days following application of the product and to persist for 4 weeks.

Reduction of the risk of transmission infection of the pathogen *Leishmania infantum*, thereby reducing the risk of canine leishmaniosis by repellent (anti-feeding) activity on sandflies *(Phlebotomus perniciosus*) for up to 3 weeks.
The effect is indirect due to product's activity against the vector.

3.3 Contraindications

In the absence of available data, the product should not be used on puppies of less than 7 weeks of age.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use on cats. Permethrin is dangerous to cats.

3.4 Special warnings

The product remains effective if the animal becomes wet. However, prolonged, intense exposure to water should be avoided. In cases of frequent water exposure the persistent efficacy may be reduced. In these cases do not retreat more frequently than once weekly. If a dog requires a shampoo, it should be administered before applying the veterinary medicinal product or at least 2 weeks after application, to optimise efficacy of the product.

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

In the absence of risk of co-infection with fleas, ticks and/or sandflies, a narrow spectrum product should be used.

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.
To reduce re-infestation from emergence of new fleas, it is recommended to treat all dogs in a household. Other animals living in the same household should also be treated with a suitable veterinary medicinal product. To aid further in reducing environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developmental stages is recommended.

Resistance to permethrin has been reported in fleas, ticks (*Rhipicephalus sanguineus*), in stable flies (*Stomoxys calcitrans*), mosquitoes (*Culex pipiens, Aedes aegypti*) and sand flies (*Phlebotomus papatasi*). The use of this product should take into account local information about susceptibility of the target parasites, where available. It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method. Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

Ticks already on the dog may not be killed within two days after treatment and may remain attached and visible. Therefore, the removal of ticks already on the dog at the time of treatment is recommended, in order to prevent them from attaching and having a blood meal.

Pet fleas often infest their beds, sleeping areas and usual resting areas like rugs and sofas. In the event of a massive infestation, start of treatment, these places will be treated, with a suitable insecticide and vacuumed regularly.

There may be an attachment of single ticks or bites by single sand flies or mosquitoes. For this reason, a transmission of infectious diseases by these parasites cannot be completely excluded if conditions are unfavourable.

It is recommended to apply the treatment at least 3 days before expected exposure to *E. canis*. With regard to *E. canis*, studies have demonstrated a reduced risk of canine ehrlichiosis in dogs exposed to *Rhipicephalus sanguineus* ticks infected with *E. canis* from 3 days following application of the product and to persist for 4 weeks.

Immediate protection against sandflies bites is not documented. Treated dogs for the reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies, *Phlebotomus perniciosus*, should be kept in a protected environment during the first 24 hours after the initial treatment application.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Only apply to undamaged skin.
Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the recipient dogs.
Care should be taken to administer the product correctly as described under section 3.9. In particular oral uptake due to the licking of the application site by treated or in-contact animals should be avoided. Accidental oral uptake may result in transient vomiting and neurological signs such as tremor and incoordination. Treatment should be symptomatic. There is no known specific antidote.
Do not use on cats. This product is extremely poisonous to cats and could be fatal due to the unique physiology of cats which is unable to metabolise certain compounds including permethrin. To prevent cats from being accidentally exposed to the product, keep treated dogs away from cats after treatment until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog, which has been treated with this product. Seek veterinary advice immediately if this occurs.
Consult your veterinary surgeon before using the product on sick and debilitated dogs.

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

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.
People with known skin sensitivity may be particularly sensitive to this product.
The predominant clinical symptoms that in extremely rare case may be shown are transient sensory irritations of the skin like tingling, burning sensation or numbness.
Avoid contact between the product and skin, eyes or mouth.
Do not eat, drink or smoke during application.
In case of accidental spillage onto skin, wash off immediately with soap and water.
If the product gets accidentally into the eyes, they should be thoroughly flushed with water. If skin or if eye irritation persists obtain medical attention immediately and show the package insert to the physician.
Do not ingest. In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.
Treated animals should not be handled for at least 12 hours after application of the product. It is therefore recommended to treat the animal in the evening. Treated animals should not be allowed to sleep with their owners, especially children.
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.
Wash hands thoroughly after use.

Special precautions for the protection of the environment:

Imidacloprid and Permethrin are toxic for aquatic organisms. Treated dogs should not be allowed to enter surface water for 48 hour after treatment, to avoid adverse effects on aquatic organisms.

Other precautions:

The solvent in the 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

Dogs:

Uncommon (1 to 10 animals / 1,000 animals treated):	Application site itching, application site hair change (e.g. application site greasy fur) Emesis
Rare (1 to 10 animals / 10,000 animals treated):	Application site erythema, application site inflammation, application site hair loss Diarrhoea
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Increased skin sensitivity (scratching, rubbing)[1] Lethargy[1] Behavioural disorder (agitation, restlessness, whining, rolling)[1, 2, 3] Digestive tract disorder (hypersalivation decreased appetite)[1, 2, 3] Neurological signs (e.g. abnormal movement, twitching)[1, 2, 3]

[1] generally self-resolving, [2] transient, [3] in dogs susceptible to permethrin

Poisoning following inadvertent oral uptake in dogs is unlikely but may occur in very rare cases. In this event, neurological signs such as tremor and lethargy can occur. Treatment should be symptomatic. There is no known specific antidote.

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

The safety of the veterinary medicinal product has not been established in dogs during pregnancy, lactation, or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Spot-on solution for external use only.

To ensure a correct dosage, body weight should be determined as accurately as possible.

The minimum dose rate is 10 mg/kg bodyweight imidacloprid and 50 mg/kg bodyweight permethrin, which corresponds to a single 6 ml pipette for a dog from 40 kg to 60 kg.

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

To protect a dog over the whole sand fly season, treatment should be compliantly continued throughout.

Method of administration
Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette. Snap back the tip. Part the coat on the back of the animal at the base of the neck in front of the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin in four even spots, from the shoulder to the base of the tail of the dog, according to the following scheme.

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.

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

Pregnancy and lactation
Application of doses equivalent to 5 times the therapeutic dose in healthy adult dogs or puppies has not produced any adverse clinical signs. It is the same in puppies whose mother received 3 times the therapeutic dose of the combination imidacloprid/permethrin. The severity of the skin rash which can sometimes appear at the application site increases with overdose.

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:

QP53AC54.

4.2 Pharmacodynamics

Imidacloprid is an ectoparasiticide belonging to the chloronicotinyl group of compounds. Chemically, it can be classified as a chloronicotinyl nitroguanidine. Imidacloprid is effective against adult fleas and larval flea stages. 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 dog's

immediate surroundings are killed following contact with a treated animal. It has a high affinity for the nicotinergic acetylcholine receptors in the post-synaptic region of the central nervous system (CNS) in insects. The ensuing inhibition of cholinergic transmission in insects results in paralysis and death of the parasite.

Permethrin belongs to the type I class of pyrethroid acaricides and insecticides and also acts as repellent. Pyrethroids affect the voltage-gated sodium channels in vertebrates and non-vertebrates. Pyrethroids are so called "open channel blockers" affecting the sodium channel by slowing both the activation and the inactivation properties thus leading to hyperexcitability and death of the parasite.
In the combination of both substances, it has been shown Imidacloprid functions as the activator of arthropod ganglia and therefore increases the efficacy of permethrin.

The product provides repellent activity (anti-feeding activity) against *Phlebotomus perniciosus* (>80% for 3 weeks), mosquitoes and ticks. Field data from an endemic area showed that the product indirectly reduces the risk of transmission of *Leishmania infantum* from infected sandflies (*Phlebotomus perniciosus*) for up to 3 weeks, thereby reducing the risk of canine leishmaniosis in treated dogs.

Resistance to permethrin may develop and it is known that resistance manifests in single or multiple mutations of its primary target site, the voltage-gated sodium channels (VGSC), commonly referred to as knockdown resistance (kdr- or skdr-mutation). Other mechanisms of resistance development include cuticle thickening and metabolic resistance via over expression of metabolizing P450 mono-oxygenases, esterases, and glutathione-S-transferases.

4.3 Pharmacokinetics

The product is indicated for dermal administration. Following topical application in dogs, the solution rapidly distributes over the body surface of the animal. Both active substances remain detectable on the skin and hair of the treated animal for 4 weeks.
Acute dermal studies in the rat and target animal overdose and serum kinetic studies have established that systemic absorption of both active substances after application on intact skin is low, transient and not relevant for the clinical efficacy.

Environmental properties

The product should not be allowed to enter watercourses as this may be dangerous for fish and aquatic organisms. For treated dogs, please see section 3.5.

Permethrin and imidacloprid containing products are toxic to honey bees.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Store in the original package.
Keep the pipette in the outer cardboard box in order to protect from light.
Do not freeze.

5.4 Nature and composition of immediate packaging

White polypropylene/COC/EVOH/polypropylene pipette with snap-off cap.

Each cardboard box contains 1, 2, 3, 4, 6 or 24 unit dose pipettes in individual PET/aluminium foil/OPA/LLDPE child-resistant sachets.

Not all pack sizes may be marketed.

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

After use, replace cap on tube.

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

The veterinary medicinal product or used container should not enter watercourses as imidacloprid and permethrin 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

Chanelle Pharmaceuticals Manufacturing Limited.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}.

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

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

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

ANNEX II

[Not applicable for MRP/DCP/SRP and national procedures]

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton (1, 2, 3, 4, 6 or 24 unit dose pipettes)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fleaguard Plus 600 mg/3000 mg Spot-on Solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each 6 ml pipette contains:
Imidacloprid 600 mg
Permethrin 40:60 3000 mg

3. PACKAGE SIZE

1, 2, 3, 4, 6 or 24 unit dose pipettes.

4. TARGET SPECIES

Dogs (from 40 kg to 60 kg).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Spot-on solution for external use only.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store in the original package.
Keep the pipette in the outer cardboard box in order to protect from light.
Do not freeze.

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

Chanelle Pharmaceuticals Manufacturing Ltd.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Sachet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fleaguard Plus 600 mg/3000 mg Spot-on Solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each 6 ml pipette contains:
Imidacloprid 600 mg
Permethrin 40:60 3000 mg

3. TARGET SPECIES

Dogs (from 40 kg to 60 kg).

4. ROUTES OF ADMINISTRATION

Spot-on solution for external use only.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use immediately.

7. SPECIAL STORAGE PRECAUTIONS

Store in the original package.
Keep the pipette in the outer cardboard box in order to protect from light.
Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Pipette

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fleaguard Plus 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each 6 ml pipette contains:
Imidacloprid 600 mg
Permethrin 40:60 3000 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use immediately.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Fleaguard Plus 600 mg/3000 mg Spot-on Solution for Dogs over 40 kg up to 60 kg

2. Composition

Each 6 ml pipette contains:

Active substances:
Imidacloprid 600 mg
Permethrin 40:60 3000 mg

Excipients:
Butylatedhydroxytoluene (E321): 6 mg

Clear yellowish to brownish solution.

3. Target species

Dogs (from 40 kg to 60 kg).

4. Indications for use

For dogs with, or at risk from mixed infestation by fleas, ticks, biting lices, sandflies and mosquitoes targeted by each of the combined active substances.
The veterinary medicinal product is only indicated when use against all the following parasite species is required at the same time.

Treatment of infestation and prevention of re-infestation by flea (*Ctenocephalides canis, Ctenocephalides felis*) due to insecticidal activity for 4 weeks.
Fleas on dogs are killed within one day following treatment. The product can be used as part of a treatment strategy for flea allergy dermatitis (FAD) suitably diagnosed by the responsible veterinarian.

Treatment of infestation by biting lice (*Trichodectes canis*).

The product has persistent acaricidal and repellent (anti-feeding) efficacy against tick infestations (*Rhipicephalus sanguineus* and *Ixodes Ricinus* for four weeks, and *Dermacentor recticulatus* for three weeks).

One treatment provides repellent (anti-feeding) activity against sand flies (*Phlebotomus papatasi* for two weeks and *Phlebotomus pernicious* for three weeks), against mosquitoes (*Aedes aegypti* for two weeks and *Culex pipiens* for four weeks) and against stable flies (*Stomoxys calcitrans*) for four weeks.

Reduction of the risk of transmission of the pathogen *Ehrlichia canis*, thereby reducing the risk of canine ehrlichiosis by acaricidal and repellent activity on the tick vector *Rhipicephalus sanguineus.*
The reduction in risk has been shown to begin from 3 days following application of the product and to persist for 4 weeks.
Reduction of the risk of transmission infection of the pathogen *Leishmania infantum*, thereby reducing the risk of canine leishmaniosis by repellent (anti-feeding) activity on sandflies *(Phlebotomus perniciosus*) for up to 3 weeks.
The effect is indirect due to product's activity against the vector.

5. Contraindications

In the absence of available data, the product should not be used on puppies of less than 7 weeks of age.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use on cats. Permethrin is dangerous to cats.

6. Special warnings

The product remains effective if the animal becomes wet. However, prolonged, intense exposure to water should be avoided. In cases of frequent water exposure the persistent efficacy may be reduced. In these cases do not retreat more frequently than once weekly. If a dog requires a shampoo, it should be administered before applying the veterinary medicinal product or at least 2 weeks after application, to optimise efficacy of the product.

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

In the absence of risk of co-infection with fleas, ticks and/or sandflies, a narrow spectrum product should be used.

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.
To reduce re-infestation from emergence of new fleas, it is recommended to treat all dogs in a household. Other animals living in the same household should also be treated with a suitable veterinary medicinal product. To aid further in reducing environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developmental stages is recommended.

Resistance to permethrin has been reported in fleas, ticks (*Rhipicephalus sanguineus*), in stable flies (*Stomoxys calcitrans*), mosquitoes (*Culex pipiens, Aedes aegypti*) and sand flies (*Phlebotomus papatasi*). The use of this product should take into account local information about susceptibility of the target parasites, where available. It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method. Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

Ticks already on the dog may not be killed within two days after treatment and may remain attached and visible. Therefore, the removal of ticks already on the dog at the time of treatment is recommended, in order to prevent them from attaching and having a blood meal.

Pet fleas often infest their beds, sleeping areas and usual resting areas like rugs and sofas. In the event of a massive infestation, start of treatment, these places will be treated, with a suitable insecticide and vacuumed regularly.

There may be an attachment of single ticks or bites by single sand flies or mosquitoes. For this reason, a transmission of infectious diseases by these parasites cannot be completely excluded if conditions are unfavourable.

It is recommended to apply the treatment at least 3 days before expected exposure to *E. canis*. With regard to *E. canis*, studies have demonstrated a reduced risk of canine ehrlichiosis in dogs exposed to *Rhipicephalus sanguineus* ticks infected with *E. canis* from 3 days following application of the product and to persist for 4 weeks.

Immediate protection against sandflies bites is not documented. Treated dogs for the reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies, *Phlebotomus perniciosus*, should be kept in a protected environment during the first 24 hours after the initial treatment application.

Special precautions for safe use in the target species:
Only apply to undamaged skin.
Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the recipient dogs.
Care should be taken to administer the product correctly as described under section 8. In particular oral uptake due to the licking of the application site by treated or in-contact animals should be avoided. Accidental oral uptake may result in transient vomiting and neurological signs such as tremor and incoordination. Treatment should be symptomatic. There is no known specific antidote.
Do not use on cats. This product is extremely poisonous to cats and could be fatal due to the unique physiology of cats which is unable to metabolise certain compounds including permethrin. To prevent cats from being accidentally exposed to the product, keep treated dogs away from cats after treatment until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog, which has been treated with this product. Seek veterinary advice immediately if this occurs.
Consult your veterinary surgeon before using the product on sick and debilitated dogs.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.
People with known skin sensitivity may be particularly sensitive to this product.
The predominant clinical symptoms that in extremely rare case may be shown are transient sensory irritations of the skin like tingling, burning sensation or numbness.
Avoid contact between the product and skin, eyes or mouth.
Do not eat, drink or smoke during application.
In case of accidental spillage onto skin, wash off immediately with soap and water.
If the product gets accidentally into the eyes, they should be thoroughly flushed with water. If skin or if eye irritation persists obtain medical attention immediately and show the package insert to the physician.
Do not ingest. In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.
Treated animals should not be handled for at least 12 hours after application of the product. It is therefore recommended to treat the animal in the evening. Treated animals should not be allowed to sleep with their owners, especially children.
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.
Wash hands thoroughly after use.

Special precautions for the protection of the environment:
Imidacloprid and Permethrin are toxic for aquatic organisms. Treated dogs should not be allowed to enter surface water for 48 hour after treatment, to avoid adverse effects on aquatic organisms.
The product should not be allowed to enter watercourses as this may be dangerous for fish and aquatic organisms.
Permethrin and imidacloprid containing products are toxic to honey bees.

Other precautions:
The solvent in the 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:
The safety of the veterinary medicinal product has not been established in dogs during pregnancy, lactation, or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

Overdose:
Pregnancy and lactation
Application of doses equivalent to 5 times the therapeutic dose in healthy adult dogs or puppies has not produced any adverse clinical signs. It is the same in puppies whose mother received 3 times the therapeutic dose of the combination imidacloprid/permethrin. The severity of the skin rash which can sometimes appear at the application site increases with overdose.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Dogs.

Uncommon (1 to 10 animals / 1,000 animals treated):	Application site itching, application site hair change (e.g. application site greasy fur) Emesis
Rare (1 to 10 animals / 10,000 animals treated):	Application site erythema, application site inflammation, application site hair loss Diarrhoea
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Increased skin sensitivity (scratching, rubbing)[1] Lethargy[1] Behavioural disorder (agitation, restlessness, whining, rolling)[1, 2, 3] Digestive tract disorder (hypersalivation decreased appetite)[1, 2, 3] Neurological signs (e.g. abnormal movement, twitching)[1, 2, 3]

[1] generally self-resolving, [2] transient, [3] in dogs susceptible to permethrin

Poisoning following inadvertent oral uptake in dogs is unlikely but may occur in very rare cases. In this event, neurological signs such as tremor and lethargy can occur. Treatment should be symptomatic. There is no known specific antidote.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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 the local representative of the marketing authorisation holder 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 solution for external use only.

To ensure a correct dosage, body weight should be determined as accurately as possible.

The minimum dose rate is 10 mg/kg bodyweight imidacloprid and 50 mg/kg bodyweight permethrin, which corresponds to a single 6 ml pipette for a dog from 40 kg to 60 kg.

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

To protect a dog over the whole sand fly season, treatment should be compliantly continued throughout.

Method of administration
Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette. Snap back the tip. Part the coat on the back of the animal at the base of the neck in front of the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin in four even spots, from the shoulder to the base of the tail of the dog, according to the following scheme.

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.

9. Advice on correct administration

Discard any opened pipettes.

10. Withdrawal periods

Not Applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in the original package.
Keep the pipette in the outer cardboard box in order to protect from light.

Do not freeze.

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

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: use immediately.

12. Special precautions for disposal

After use, replace cap on tube.

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

The veterinary medicinal product or used container should not enter watercourses as imidacloprid and permethrin 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes:
Each cardboard box contains 1, 2, 3, 4, 6 or 24 unit dose pipettes in individual foil sachets.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.
Tel: +353 91 841788

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

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

België/Belgique/Belgien
{Nom/Naam/Name}
<{Adresse/Adres/Anschrift }
BE-0000 {Localité/Stad/Stadt}>
Tél/Tel: + {N° de téléphone/Telefoonnummer/ Telefonnummer}
<{E-mail}>

Lietuva
{pavadinimas}
<{adresas}
LT {pašto indeksas} {miestas}>
Tel: +370{telefono numeris}
<{E-mail}>

Република България
{Наименование}
<{Адрес}
BG {Град} {Пощенски код}>
Тел: + 359 {Телефонен номер}
<{E-mail}>

Luxembourg/Luxemburg
{Nom}
<{Adresse}
L-0000 {Localité/Stadt}>
Tél/Tel: + {N° de téléphone/Telefonnummer}
<{E-mail}>

Česká republika
{Název}
<{Adresa}
CZ {město}>
Tel: +{telefonní číslo}
<{E-mail}>

Danmark
{Navn}
<{Adresse}
DK-0000 {by}>
Tlf: + {Telefonnummer}
<{E-mail}>

Deutschland
{Name}
<{Anschrift}
DE-00000 {Stadt}>
Tel: + {Telefonnummer}
<{E-mail}>

Eesti
(Nimi)
<(Aadress)
EE - (Postiindeks) (Linn)>
Tel: +(Telefoninumber)
<{E-mail}>

Ελλάδα
{Όνομα}
<{Διεύθυνση}
EL-000 00 {πόλη}>
Τηλ: + {Αριθμός τηλεφώνου}
<{E-mail}>

España
{Nombre}
<{Dirección}
ES-00000 {Ciudad}>
Tel: + {Teléfono}
<{E-mail}>

France
{Nom}
<{Adresse}
FR-00000 {Localité}>
Tél: + {Numéro de téléphone}
<{E-mail}>

Hrvatska
{Ime}
<{Adresa}
{Poštanski broj} {grad}>
Tel: + {Telefonski broj}
<{e-mail}>

Magyarország
{Név}
<{Cím}
HU-0000 {Város}>
Tel.: + {Telefonszám}
<{E-mail}>

Malta
{Isem}
<{Indirizz}
MT-0000 {Belt/Raħal}>
Tel: + {Numru tat-telefon}
<{E-mail}>

Nederland
{Naam}
<{Adres}
NL-0000 XX {stad}>
Tel: + {Telefoonnummer}
<{E-mail}>

Norge
{Navn}
<{Adresse}
N-0000 {poststed}>
Tlf: + {Telefonnummer}
<{E-mail}>

Österreich
{Name}
<{Anschrift}
A-00000 {Stadt}>
Tel: + {Telefonnummer}
<{E-mail}>

Polska
{Nazwa/ Nazwisko:}
<{Adres:}
PL – 00 000{Miasto:}>
Tel.: + {Numer telefonu:}
<{E-mail}>

Portugal
{Nome}
<{Morada}
PT-0000–000 {Cidade}>
Tel: + {Número de telefone}
<{E-mail}>

România
{Nume}
<{Adresă}
{Oraş} {Cod poştal} – RO>
Tel: + {Număr de telefon}
<{E-mail}>

Ireland
{Name}
<{Address}
IE - {Town} {Code for Dublin}>
Tel: + {Telephone number}
<{E-mail}>

Ísland
{Nafn}
<{Heimilisfang}
IS-000 {Borg/Bær}>
Sími: + {Símanúmer}
<{Netfang}>

Italia
{Nome}
<{Indirizzo}
IT-00000 {Località}>
Tel: + {Numero di telefono}>
<{E-mail}>

Κύπρος
{Όνομα}
<{Διεύθυνση}
CY-000 00 {πόλη}>
Τηλ: + {Αριθμός τηλεφώνου}
<{E-mail}>

Latvija
{Nosaukums}
<{Adrese}
{Pilsēta}, LV{Pasta indekss }>
Tel: + {Telefona numurs}
<{E-mail}>

Slovenija
{Ime}
<{Naslov}
SI-0000 {Mesto}>
Tel: + {telefonska številka}
<{E-mail}>

Slovenská republika
{Meno}
<{Adresa}
SK-000 00 {Mesto}>
Tel: + {Telefónne číslo}
<{E-mail}>

Suomi/Finland
{Nimi/Namn}
<{Osoite/Adress}
FI-00000 {Postitoimipaikka/Stad}>
Puh/Tel: + {Puhelinnumero/Telefonnummer}
<{E-mail}>

Sverige
{Namn}
<{Adress}
SE-000 00 {Stad}>
Tel: + {Telefonnummer}
<{E-mail}>

United Kingdom (Northern Ireland)
{Name}
<{Address}
{Town} {Postal code} – UK>
Tel: + {Telephone number}
<{E-mail}>>

<17. Other information>