ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DIPTRON PLUS 268 mg/2400 mg spot-on solution for large dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4.4 ml pipette contains:

Active substances:

Fipronil	268.40 mg
Permethrin (40:60)	2398.00 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butylhydroxyanisole (E320)	0.88 mg
Butylhydroxytoluene (E321)	0.44 mg
Benzyl alcohol (E1519)	
Diethylene glycol monoethyl ether	

Clear yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

In dogs, to be used against infestations with fleas and/or ticks when repellent (anti-feeding) activity is also necessary against sand-flies and/or mosquitoes.

Fleas:
Treatment and prevention of infestations by fleas (*Ctenocephalides felis*). Fleas on dogs are killed within 24 hours following treatment. One treatment provides persistent efficacy against new infestations with adult fleas for 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 condition has previously been diagnosed by a veterinarian.

Ticks:
Treatment of infestations with *Ixodes ricinus* ticks.
One application provides four weeks persistent acaricidal efficacy against tick infestations (*Ixodes ricinus, Dermacentor reticulatus* and *Rhipicephalus sanguineus*).
If ticks of some species (*Dermacentor reticulatus* or *Rhipicephalus sanguineus*) are present at the time of application, not all ticks may be killed within 48 hours.

Sand-flies and mosquitoes:

One treatment provides repellent (anti-feeding) activity against sand-flies (*Phlebotomus perniciosus*) and against mosquitoes (*Culex pipiens*, *Aedes aegypti*) for four weeks.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use on rabbits and cats as adverse reactions and even death can occur (see also section 3.5).
Do not use on sick (e.g. systemic diseases, fever…) or convalescent animals.

3.4 Special warnings

The veterinary medicinal product remains effective after exposure to sunlight or if the animal becomes wet after rain.
Avoid frequent swimming or shampooing of treated dogs as this may adversely affect maintenance of veterinary medicinal product effectiveness.

A dog with fleas may show an allergic reaction to the flea saliva called Flea Allergy Dermatitis (FAD). If your dog has inflamed skin, is itchy and bites, scratches excessively and is restless and uncomfortable, you should seek the advice of a veterinarian to diagnose if your dog suffers from FAD.

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. Fleas from pets often infest the animal's basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated, in case of massive infestation and at the beginning of the control measures, 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, the transmission of infectious diseases by these parasites cannot be excluded if conditions are unfavourable.

Studies have shown anti-feeding effect of four weeks for sand-flies and mosquitoes. Therefore, for short-term travel (less than 4 weeks) to endemic areas it is recommended to apply the treatment immediately before expected exposure. For longer-term exposure (e.g. animals living in endemic areas or travel duration longer than 4 weeks), the treatment schedule should be based on local epidemiological information.

Unnecessary use of antiparasitics or use deviating from the instructions given in the *Summary of Product Characteristics* may increase the resistance selection pressure and lead to reduced efficacy. Parasite resistance to any particular class of ectoparasiticides may be developed following frequent, repeated use of an ectoparasiticide of that class. Therefore, the use of this veterinary medicinal product should be based on the assessment of each individual case and on local epidemiological information about the current susceptibility of the target species in order to limit the possibility of a future selection for resistance.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Animals should be weighed accurately prior to treatment.
The safety of the veterinary medicinal product has not been established in dogs younger than 12 weeks of age or in dogs weighing less than 1.5 kg.

Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the recipient dogs. In particular oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.

This veterinary medicinal product is extremely poisonous to cats and could be fatal. In case of accidental dermal exposure, wash the cat with shampoo or soap, and seek veterinary advice rapidly. To prevent cats from being accidentally exposed to the veterinary medicinal 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 veterinary medicinal product. In case of exposure of this type, seek veterinary advice immediately if this occurs.
Do not use on rabbits and cats.

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

The veterinary medicinal product may cause neurotoxicity. The veterinary medicinal product may be harmful if swallowed. Avoid ingestion including hand-to-mouth contact. In the event of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
This veterinary medicinal product can cause eye and mucous membrane irritation. Therefore, avoid contact between the veterinary medicinal product and the mouth or eyes including hand-to-mouth and hand-to-eye contacts. In the event of accidental contact between the veterinary medicinal product and eyes, immediately and thoroughly flush the eyes with water. If eye irritation persists, seek medical advice and show the package leaflet or the label to the physician.
Avoid contact with the skin. Should the veterinary medicinal product come into contact with skin, wash the contacted area immediately with soap and water.
Wash hands thoroughly after use.
Do not eat, drink or smoke while handling the veterinary medicinal product.
People with a known hypersensitivity (allergy) to fipronil, permethrin or any of the other ingredients should avoid contact with the veterinary medicinal product, which, on very rare occasions, can cause respiratory irritation and dermal reactions in certain individuals.
Should symptoms occur, seek medical advice immediately and show the leaflet or the label to the physician.
Treated animals should not be handled or played with until the application site is dry and for about 12 hours after treatment. It is therefore recommended to treat the animals in the early evening or late afternoon in order to minimise contact with the treated animal. On the day of treatment, treated animals should not be permitted to sleep with their owner, especially children.
Keep the stored pipettes in the original packaging. In order to prevent children from getting access to used pipettes, dispose of used pipettes immediately in a proper way.

Special precautions for the protection of the environment:

Fipronil and permethrin may adversely affect aquatic organisms. Dogs should not be allowed to swim in water courses for 2 days after application.

Other precautions:

The veterinary medicinal product may have adverse effects on painted, varnished or other household surfaces or furnishings. Allow the application site to dry before permitting contact with such materials.

3.6 Adverse events

Dog:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site pruritus[1], application site erythema[1], application site alopecia[1] Pruritus Behavioural changes: hyperactivity, agitation. Neurological disorders: lethargy, muscle tremor, convulsions, ataxia Vomiting
Undetermined frequency (it could not be estimated according to the available data)	Hypersalivation[1,2]

[1] Transient
[2] If licking occurs

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 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:

Laboratory studies in dogs have not produced any evidence of teratogenic or embryotoxic effect. The safety of the veterinary medicinal product has not been established during pregnancy and lactation. 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

For external use only.
Spot-on use.

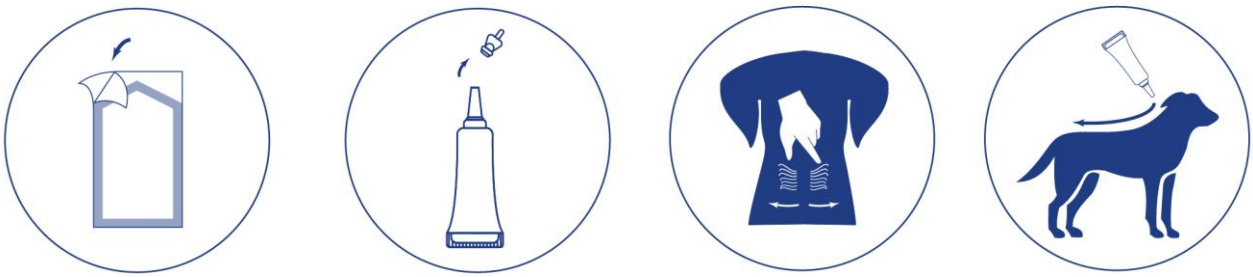
Dosage:
The recommended minimum dose is 6.7 mg fipronil/kg b.w and 60 mg permethrin/kg b.w..

Dog weight	Fipronil (mg)	Permethrin (mg)
1.5-4 kg	26.8	240
4-10 kg	67	600
10-20 kg	134	1200
20-40 kg	268	2400

For dogs > 40 kg the appropriate combination of pipettes should be used.

Method of administration

Remove the pipette from the aluminium sachet. Hold the pipette upright. Tap the narrow part of the pipette to ensure that the contents are within the main body of the pipette. Break the snap-off top of the spot-on pipette along the scored line.
Part the pet's coat until its skin is visible. Place the tip of the pipette directly against the bared skin and squeeze gently several times to empty its contents at two to four different points, depending on body weight, along the pet's back from the shoulder to the base of the tail.
As a guide, dogs under 20 kg should have the veterinary medicinal product applied in two spots, whereas those over 20 kg should receive the veterinary medicinal product in 2-4 spots.



Treatment schedule:
The use of the veterinary medicinal product should be based on a confirmed infestation or risk of infestation, with fleas and/or ticks when repellent (anti-feeding) activity is also necessary against sand-flies and/or mosquitoes.
Depending on the ectoparasite challenge, the responsible veterinary surgeon may recommend repeating the treatment. The interval between two treatments should be at least 4 weeks.

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

Safety has been demonstrated with up to 5 times the maximum recommended dose in healthy 12-week old puppies treated 3 times at intervals of 3 weeks.
The risk of experiencing adverse reactions (see section 3.6) may however increase with overdosing, so animals should always be treated with correct pipette size according to bodyweight.

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

The product is an ectoparasiticide for topical use containing fipronil and permethrin. This combination acts as an insecticide, acaricide and as a repellent to sand-flies and mosquitoes.

Fipronil is an insecticide and acaricide belonging to the phenylpyrazole family. Fipronil and its metabolite fipronil sulfone act at ligand-gated chloride channels, in particular those gated by the neurotransmitter gamma-aminobutyric acid (GABA) as well as desensitising (D) and non-desensitising (N) channels gated by glutamate (Glu, unique invertebrate ligand-gated chloride channels), thereby blocking pre- and post-synaptic transfer of chloride ions across cell membranes. This results in uncontrolled activity of the central nervous system and death of insects or acari.

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.

The product provides an immediate and persistent insecticidal activity against fleas (*Ctenocephalides felis*), immediate acaricidal activity against Ixodes ricinus ticks, persistent acaricidal activity against ticks (*Rhipicephalus sanguineus, Dermacentor reticulatus* and *Ixodes ricinus*) and repellent (anti-feeding) activity against sand-flies (*Phlebotomus perniciosus*) and mosquitoes (*Culex pipiens, Aedes aegypti*).

When applied to dogs at least 2 days prior to tick exposure, the product was experimentally shown to indirectly reduce the risk of *Babesia canis canis* transmission from infected ticks *Dermacentor reticulatus* until 28 days after application, thereby reducing the risk of canine babesiosis in treated dogs.

4.3 Pharmacokinetics

The major metabolite of Fipronil is the sulfone derivative, which also possesses insecticidal and acaricidal properties.
Following topical application to dogs, under the normal conditions of use:
- Permethrin and fipronil, together with its major metabolite, are well distributed in the haircoat of the dog within one day after application. The concentrations of fipronil, fipronil sulfone and permethrin in the haircoat coat decrease with time and are detectable for at least 35 days after application.
- Fipronil plasma concentrations peak after 5 days whereas its active metabolite peaks around 14 days. Concentrations are quantifiable up to 35 days. Permethrin displays very low levels of systemic absorption.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Keep the pipette in the aluminium sachet in order to protect from light.

5.4 Nature and composition of immediate packaging

4,4 ml white opaque spot-on multi-layer (high density polyethylene/ ethylene-methyl acrylate/ ethylene vinyl alcohol/Ethylene methyl acrylate/high density polyethylene or mixture) pipette with a low density polyethylene head. Each pipette is packaged in a heat-sealed aluminium sachet.

Pack sizes:
Boxes of 1, 2, 3, 4, 5, 6, 8, 10, 12, 24, 30,60, 90, 120 or 150 pipettes in carton box.

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 Fipronil-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

QUIMICA DE MUNGUIA, S.A

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 not subject to prescription.

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

DIPTRON PLUS 268 mg/2400 mg spot-on solution for large dogs

Box containing pipettes placed in individual aluminium sachet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DIPTRON PLUS 268 mg/2400 mg spot-on solution for large dogs
Dog 20 – 40 kg

2. STATEMENT OF ACTIVE SUBSTANCES

Each pipette contains:

		Fipronil	Permethrin
0.44 ml	1.5 – 4 kg	26.8 mg	240 mg
1.10 ml	4 – 10 kg	67 mg	600 mg
2.20 ml	10 – 20 kg	134 mg	1200 mg
4.40 ml	20 – 40 kg	268 mg	2400 mg

Clear yellow solution.
For dogs > 40 kg the appropriate combination of pipettes should be used.

3. PACKAGE SIZE

1, 2, 3, 4, 5, 6, 8, 10, 12, 24, 30,60, 90, 120 or 150 pipettes.

4. TARGET SPECIES

Dogs 20 – 40 kg

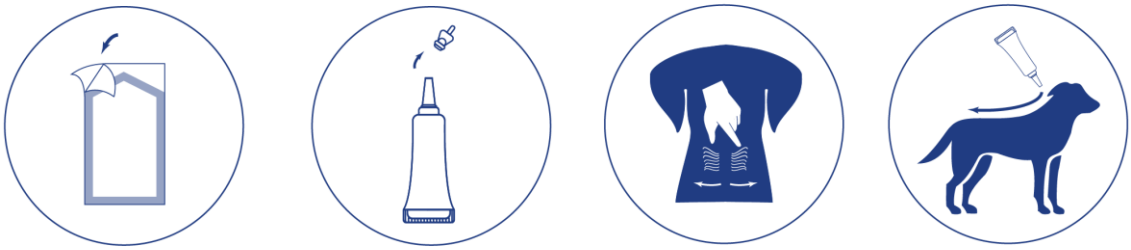
5. INDICATIONS

In dogs, to be used against infestations with fleas and/or ticks when repellent (anti-feeding) activity is also necessary against sand-flies and/or mosquitoes.

Fleas & Ticks + Sand-flies & mosquitoes

6. ROUTES OF ADMINISTRATION

Spot-on use.



7. WITHDRAWAL PERIODS

8. EXPIRY DATE

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

9. SPECIAL STORAGE PRECAUTIONS

Keep the blister pack in the outer carton to protect from light.

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

QUIMICA DE MUNGUIA, S.A.

14. MARKETING AUTHORISATION NUMBERS

EU/0/00/000/000

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

DIPTRON PLUS 268 mg/2400 mg spot-on solution for large dogs

COEX PIPETTES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DIPTRON PLUS 268 mg/2400 mg spot-on solution for large dogs
Dog 20-40 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Fipronil 268 mg
Permethrin 2400 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

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

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

DIPTRON PLUS 268 mg/2400 mg spot-on solution for large dogs

Aluminium sachet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DIPTRON PLUS 268 mg/2400 mg spot-on solution for large dogs
Dog 20-40 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Fipronil 268 mg
Permethrin 2400 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

DIPTRON PLUS 26.8 mg/240 mg spot-on solution for very small dogs
DIPTRON PLUS 67 mg/600 mg spot-on solution for small dogs
DIPTRON PLUS 134 mg/1200 mg spot-on solution for medium dogs
DIPTRON PLUS 268 mg/2400 mg spot-on solution for large dogs
Fipronil/Permethrin

2. Composition

Each pipette contains:

	Active substances		Excipients:		
	Fipronil	Permethrin	Butylhydroxyanisole (E320)	Butylhydroxytoluene (E321)	Excipients*
DIPTRON PLUS for very small dogs	26.84 mg	239.8 mg	0.088 mg	0.044 mg	q.s.p. 0.44 ml
DIPTRON PLUS for small dogs	67.1 mg	599.5 mg	0.22 mg	0.11 mg	q.s.p. 1.1 ml
DIPTRON PLUS for medium dogs	134.2 mg	1199.0 mg	0.44 mg	0.22 mg	q.s.p. 2.2 ml
DIPTRON PLUS for large dogs	268.4 mg	2398.0 mg	0.88 mg	0.44 mg	q.s.p. 4.4 ml

*Other excipients: Benzyl alcohol (E1519) and Diethylene glycol monoethyl ether

Clear yellow solution.

3. Target species

Dogs

4. Indications for use

In dogs, to be used against infestations with fleas and/or ticks when repellent (anti-feeding) activity is also necessary against sand-flies and/or mosquitoes.

Fleas:
Treatment and prevention of infestations by fleas (*Ctenocephalides felis*). Fleas on dogs are killed within 24 hours following treatment. One treatment provides persistent efficacy against new infestations with adult fleas for four weeks. The product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD) where this condition has previously been diagnosed by a veterinarian.

Ticks:
Treatment of infestations with *Ixodes ricinus* ticks.
One application provides four weeks persistent acaricidal efficacy against tick infestations (*Ixodes ricinus, Dermacentor reticulatus* and *Rhipicephalus sanguineus*).
If ticks of some species (*Dermacentor reticulatus* or *Rhipicephalus sanguineus*) are present at the time of application, not all the ticks may be killed within 48 hours.

Sand-flies and mosquitoes:

One treatment provides repellent (anti-feeding) activity against sand-flies (*Phlebotomus perniciosus*) and against mosquitoes (*Culex pipiens, Aedes aegypti*) for four weeks.

5. Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the other ingredients.
Do not use on rabbits and cats as adverse reactions and even death can occur (see also section *Special precautions for use in animals*).
Do not use on sick (e.g. systemic diseases, fever,…) or convalescent animals.

6. Special warnings

Special warnings:

The veterinary medicinal product remains effective after exposure to sunlight or if the animal becomes wet after rain.
Avoid frequent swimming or shampooing of treated dogs as this may adversely affect maintenance of product effectiveness.

A dog with fleas may show an allergic reaction to the flea saliva called Flea Allergy Dermatitis (FAD). If your dog has inflamed skin, is itchy and bites, scratches excessively and is restless and uncomfortable, you should seek the advice of a veterinarian to diagnose if your dog suffers from FAD.

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 product. Fleas from pets often infest the animal's basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated, in case of massive infestation and at the beginning of the control measures, 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, the transmission of infectious diseases by these parasites cannot be excluded if conditions are unfavourable.

Studies have shown anti-feeding effect of four weeks for sand-flies and mosquitoes. Therefore, for short-term travel (less than 4 weeks) to endemic areas it is recommended to apply the treatment immediately before expected exposure. For longer-term exposure (e.g. animals living in endemic areas or travel duration longer than 4 weeks), the treatment schedule should be based on local epidemiological information.

Special precautions for safe use in the target species:

Animals should be weighed accurately prior to treatment.
The safety of the product has not been established in dogs younger than 12 weeks of age or in dogs weighing less than 1.5 kg.
Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the recipient dogs. In particular oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.

This product is extremely poisonous to cats and could be fatal. In case of accidental dermal exposure, wash the cat with shampoo or soap, and seek veterinary advice rapidly. 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. In case of exposure of this type, seek veterinary advice immediately if this occurs.
Do not use on rabbits and cats.

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

The product may cause neurotoxicity. The product may be harmful if swallowed. Avoid ingestion including hand-to-mouth contact. In the event of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
This product can cause eye and mucous membrane irritation. Therefore, avoid contact between the product and the mouth or eyes including hand-to-mouth and hand-to-eye contacts. In the event of accidental contact between the product and eyes, immediately and thoroughly flush the eyes with water. If eye irritation persists, seek medical advice and show the package leaflet or the label to the physician.
Avoid contact with the skin. Should the product come into contact with skin, wash the contacted area immediately with soap and water.
Wash hands thoroughly after use.
Do not eat, drink or smoke while handling the veterinary medicinal product.
People with a known hypersensitivity (allergy) to fipronil, permethrin or any of the other ingredients should avoid contact with the veterinary medicinal product, which, on very rare occasions, can cause respiratory irritation and dermal reactions in certain individuals.
Should symptoms occur, seek medical advice immediately and show the leaflet or the label to the physician.
Treated animals should not be handled or played with until the application site is dry and for about 12 hours after treatment. It is therefore recommended to treat the animals in the early evening or late afternoon in order to minimise contact with the treated animal. On the day of treatment, treated animals should not be permitted to sleep with their owner, especially children.
Keep the stored pipettes in the original packaging. In order to prevent children from getting access to used pipettes, dispose of used pipettes immediately in a proper way.

Special precautions for the protection of the environment:

Fipronil and permethrin may adversely affect aquatic organisms. Dogs should not be allowed to swim in water courses for 2 days after application.

Other precautions:

The product may have adverse effects on painted, varnished or other household surfaces or furnishings. Allow the application site to dry before permitting contact with such materials.

Pregnancy and lactation:

Laboratory studies in dogs have not produced any evidence of teratogenic or embryotoxic effect. The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

Safety has been demonstrated with up to 5 times the maximum recommended dose in healthy 12-week old puppies treated 3 times at intervals of 3 weeks.
The risk of experiencing adverse reactions (see section 'ADVERSE REACTIONS') may however increase with overdosing, so animals should always be treated with correct pipette size according to bodyweight.

7. Adverse events

Dog:

Very rare *(<1 animal / 10,000 animals treated, including isolated reports):*	*Application site pruritus[1], application site erythema[1], application site alopecia[1]* *Pruritus* *Behavioural changes: hyperactivity, agitation.* *Neurological disorders: lethargy, muscle tremor, convulsions, ataxia* *Vomiting*
Undetermined frequency (it could not be estimated according to the available data)	*Hypersalivation[1,2]*

[1] *Transient*
[2] *If licking occurs*

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 using the contact details at the end of this leaflet, or via your national reporting system: <{national system details}*[listed in Appendix I*]*>.

*[*For the printed material, please refer to the guidance of the annotated QRD template.]*

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

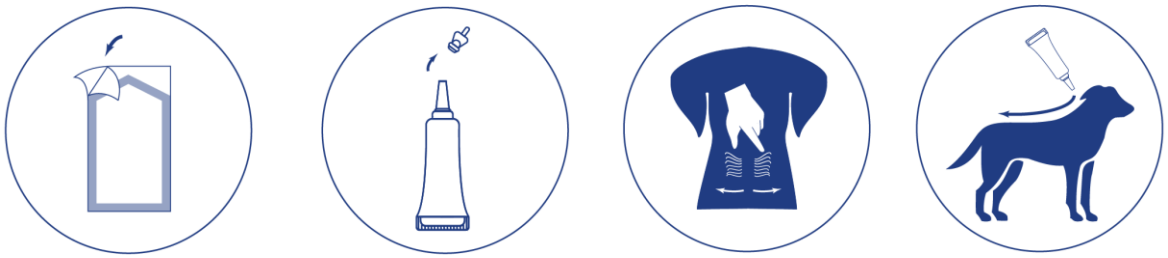
For external use only.
Spot-on use.

Dosage:
The recommended minimum dose is 6.7 mg fipronil /kg b.w.and 60 mg permethrin/kg b.w.

Dog weight	Fipronil (mg)	Permethrin (mg)
1.5 – 4 kg	26.8	240
4 – 10 kg	67	600
10 – 20 kg	134	1200
20 – 40 kg	268	2400

For dogs > 40 kg the appropriate combination of pipettes should be used.

Method of administration:
Remove the pipette from the aluminium sachet. Hold the pipette upright. Tap the narrow part of the pipette to ensure that the contents are within the main body of the pipette. Break the snap-off top of the spot-on pipette along the scored line.
Part the pet's coat until its skin is visible. Place the tip of the pipette directly against the bared skin and squeeze gently several times to empty its contents at two to four different points, depending on body weight, along the pet's back from the shoulder to the base of the tail.
As a guide, dogs under 20 kg should have the product applied in two spots, whereas those over 20 kg should receive the product in 2-4 spots.



9. Advice on correct administration

Treatment schedule:
The use of the product should be based on a confirmed infestation or risk of infestation, with fleas and/or ticks when repellent (anti-feeding) activity is also necessary against sandflies and/or mosquitoes.
Depending on the ectoparasite challenge the responsible veterinary surgeon may recommend repeating the treatment. The interval between two treatments should be at least 4 weeks (see also section *Overdose*).

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the pipette in the aluminium sachet in order to protect from light.

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

Shelf-life after first opening the immediate packaging: use immediately.

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 Fipronil-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 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

14. Marketing authorisation numbers and pack sizes

Marketing authorization number

Pack sizes
Boxes of 1, 2, 3, 4, 5, 6, 10, 12, 24, 30, 60, 90, 120 or 150 pipettes in carton box.

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 (https://medicines.health.europa.eu/veterinary).

16. Contact details

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

QUIMICA DE MUNGUIA, S.A
Derio Bidea, 51. 48100 Munguía.
Vizcaya (Spain)

<17. Other information>

Only for those countries where expanded text is proposed