ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CERTIFECT 67 mg/ 60.3 mg/ 80 mg spot-on solution for dogs 2-10 kg
CERTIFECT 134 mg/ 120.6 mg/ 160 mg spot-on solution for dogs 10-20 kg
CERTIFECT 268 mg/ 241.2 mg/ 320 mg spot-on solution for dogs 20-40 kg
CERTIFECT 402 mg/ 361.8 mg/ 480 mg spot-on solution for dogs 40-60 kg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:
Each unit dose delivers:

CERTIFECT spot-on solution	Volume of unit dose (ml)	Fipronil (mg)	(S)-Methoprene (mg)	Amitraz (mg)
dogs 2-10 kg	1.07	67	60.3	80
dogs 10-20 kg	2.14	134	120.6	160
dogs 20-40 kg	4.28	268	241.2	320
dogs 40-60 kg	6.42	402	361.8	480

Excipients:
Butylhydroxyanisole (0.02 %)
Butylhydroxytoluene (0.01 %)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution.
Clear amber to yellowish solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

Treatment and prevention of infestations in dogs by ticks (*Ixodes ricinus, Dermacentor reticulatus, Rhipicephalus sanguineus, Ixodes scapularis, Dermacentor variabilis, Haemaphysalis elliptica, Haemaphysalis longicornis, Amblyomma americanum* and *Amblyomma maculatum)* and fleas *(Ctenocephalides felis* and *Ctenocephalides canis).*

Treatment of infestations by chewing lice (*Trichodectes canis*).

Prevention of environmental flea contamination by inhibiting the development of all flea immature stages. The product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD). Elimination of fleas and ticks within 24 hours. One treatment prevents further infestations for 5 weeks by ticks and for up to 5 weeks by fleas.

The treatment indirectly reduces the risk of transmission of tick-borne diseases (canine babesiosis, monocytic ehrlichiosis, granulocytic anaplasmosis and borreliosis) from infected ticks for 4 weeks.

4.3 Contraindications

Do not use on sick (e.g. systemic diseases, diabetes, fever) or convalescent animals.
Do not use in rabbits and cats.

4.4 Special warnings for each target species

The veterinary medicinal product remains effective after exposure to sunlight or if the animal becomes wet after rain, bathing, or water immersion. However, shampooing or immersion of the animal in water directly after treatment or frequent shampooing may reduce the duration of activity. In these cases do not treat more frequently than once a fortnight. Treated animals should not be bathed until 48 hours after treatment. If the dog requires shampooing, it is better to do so before applying the veterinary medicinal product.

All stages of fleas can infest the dog's basket, bedding and regular resting areas such as carpets and soft furnishings. In case of massive flea infestation and at the beginning of the control measures these areas should be treated with a suitable environmental product and then vacuumed regularly.

After treatment with CERTIFECT ticks will generally be killed and fall off the dog within 24 hours after infestation without having a blood meal. However the attachment of single ticks after treatment cannot be excluded. For this reason the transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.

4.5 Special precautions for use

Special precautions for use in animals

Avoid contact with the dog's eyes.

Spot-on application only. Do not administer orally or via any other route.
The treated area may appear wet or oily after treatment.
In the absence of additional safety studies, do not repeat the treatment at intervals of less than 2 weeks, do not treat puppies less than 8 weeks of age, and dogs less than 2 kg bodyweight (b.w.).

This veterinary medicinal product contains amitraz, which is a monoamine oxidase inhibitor (MAOI); therefore, in the absence of studies, this veterinary medicinal product should not be used on dogs treated with MAOI.
Dogs should be prevented from accessing streams and rivers for 48-hours following treatment (see section 6.6).

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

This veterinary medicinal product may cause skin sensitisation, allergic reactions and mild eye irritation in humans. Animals or persons with a known hypersensitivity to any of the active ingredients or excipients should avoid contact which, on very rare occasions, can cause respiratory irritation and dermal reactions in certain individuals. The use of protective gloves is recommended. Avoid direct contact with the application site. Children should not be allowed to play with treated dogs until the application site is dry. It is therefore recommended that dogs are not treated during the day, but during the early evening, and that recently treated animals are not allowed to sleep with owners, especially children.

This veterinary medicinal product contains amitraz, which can lead to neurological side-effects in humans. Amitraz is a monoamine oxidase inhibitor (MAOI); therefore, people taking MAOI-containing medication should take particular care and avoid direct contact with the product.
To minimise the potential for inhalation, apply in the open air or in a well ventilated area.
Do not smoke, drink or eat whilst handling.
Wash hands thoroughly after use.
Used pipettes should be disposed of immediately. Stored pipettes must be kept in the intact foil package.
In case of accidental spillage onto skin, wash off immediately with soap and water. If it accidentally gets into the eyes, they should be thoroughly flushed with water.
In case of incorrect use, seek medical advice immediately and show the package leaflet or the label to the physician.
If side effects are noted, seek immediate medical assistance and show the package leaflet or label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Transient skin reactions at the application site (skin discolouration, local hair loss, itching, redness) and general itching or hair loss may occur on rare occasions. Lethargy, ataxia, emesis, anorexia, diarrhoea, excessive salivation, hyperglycaemia, increased sensitivity to stimulation, bradycardia or bradypnea may be observed. Signs are transitory and generally resolve without treatment within 24 hours.

In very rare instances, certain sensitive dogs may develop skin irritation at the application site. Other forms of dermatitis including pemphigus-like conditions may occur in even rarer instances. Should this occur, contact your veterinarian promptly for treatment advice and discontinue use of the product.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Safety was demonstrated in breeding, pregnant and lactating animals treated at 28-day intervals with multiple consecutive doses of up to 3 times the maximum recommended dose.
Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

No data available.

4.9 Amounts to be administered and administration route

Dose:
The recommended minimum dose is 6.7 mg/kg bodyweight for fipronil, 6 mg/kg for (S)-methoprene and 8 mg/kg for amitraz.

Each unit dose (dual cavity pipette) delivers:

CERTIFECT spot-on solution	Volume of unit dose (ml)	Fipronil (mg)	S-methoprene (mg)	Amitraz (mg)
dogs 2-10 kg	1.07	67	60.3	80
dogs 10-20 kg	2.14	134	120.6	160
dogs 20-40 kg	4.28	268	241.2	320
dogs 40-60 kg	6.42	402	361.8	480

Treatment schedule:
Monthly intervals throughout the tick and/or flea seasons, based on local epidemiological situations.

Advice on correct administration:
Select the appropriate pipette size for the weight of the dog. For dogs over 60 kg, use the appropriate combination of two pipettes that most closely matches the bodyweight.

Method of administration:
Spot-on use.
For a pack of 3, first separate one blister from the others by tearing along the perforation.
Use a pair of scissors to cut the blister along the dotted line (or fold on the corner as shown and pull the foil away).
Remove the pipette and hold it upright.
Cut off the pipette tip with a pair of scissors. Part the coat until the skin is visible. Place the tip of the pipette on the skin. Squeeze the pipette, apply about half of the contents half way down the neck between the base of the skull and the shoulder blades. Repeat the application at the base of the neck in front of the shoulder blades to empty the pipette.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Safety has been demonstrated with up to 5 times the recommended dose in healthy adult dogs (treated up to 6 times at two-week intervals) and in puppies (aged 8 weeks treated once).
Safety was also demonstrated in breeding, pregnant and lactating animals treated at 28-day intervals with multiple consecutive doses of up to 3 times the maximum recommended dose.
The risk of experiencing adverse reactions (see section 4.6) may however increase with overdosing, so animals should always be treated with the correct pipette size according to bodyweight.

Known side-effects of amitraz and its metabolites are due to alpha-2-adreno-receptor agonist effects. They may consist of hypersalivation, vomiting, lethargy, hyperglycaemia, bradycardia or bradypnea. Signs are transitory and generally resolve without treatment within 24 hours.
If symptoms are severe or persist, alternatively the antidote alpha-2-adreno-receptor antagonist atipamezole hydrochloride may be used.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other ectoparasiticides for topical use.
ATCvet code: QP53AX65.

The veterinary medicinal product is an insecticidal and acaricidal solution for topical use, containing adulticidal active ingredients, fipronil and amitraz, in combination with an ovicidal and larvicidal active ingredient, (S)-methoprene.

5.1 Pharmacodynamic properties

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.

(S)-Methoprene is an insect growth regulator (IGR) of the class of compounds known as juvenile hormone analogues that inhibit the development of immature stages of insects. This compound mimics the action of juvenile hormone and causes impaired development and death of the developing stages of fleas. The on-animal ovicidal activity of (S)-methoprene results from either direct penetration of the eggshell of newly laid eggs or from absorption through the cuticle of the adult fleas. (S)-methoprene is also effective in preventing flea larvae and pupae from developing, which prevents contamination of the environment of the treated animals with the immature stages of fleas.

Amitraz is a formamidine acaricide that acts as an agonist on octopamine receptors causing an over-stimulation of octopaminergic synapses in acari, resulting in tremors and convulsions. Moreover, at sublethal concentrations these compounds have the ability to cause anorexia in acari and suppress their reproduction. Specific tick detachment properties described as an expellant action causing ticks to withdraw their mouthparts rapidly and fall off the host animal have been reported for amitraz.

The combination of amitraz and fipronil acts on multiple sites of the nervous systems of ticks. A low dose of amitraz together with fipronil has shown synergistic efficacy against ticks resulting in an increased speed of kill (starting at 2 hours and greater than 90 % at 24 hours) and a longer duration of activity when compared to the active substances administered alone.

CERTIFECT treatment causes detachment of ticks when applied to a dog with a pre-existing infestation, disrupts attachment and rapidly kills ticks within 24 hours thus inhibiting the blood meal and the concomitant risk of transmission of tick-borne pathogens. The risk of developing canine babesiosis, monocytic ehrlichiosis, granulocytic anaplasmosis and borreliosis for 4 weeks is thereby indirectly reduced.

Studies have demonstrated that there is no pharmacodynamic and pharmacokinetic interaction in mammals between fipronil, (S)-methoprene and amitraz.

5.2 Pharmacokinetic particulars

Systemic absorption of CERTIFECT is low for all three active substances following topical administration.
Fipronil: Absolute bioavailability: 9.5 %. The mean maximum concentration (C_{max}): 19 ng/ml in plasma found after 5 days (T_{max}). Plasma concentrations were below 1 ng/ml (limit of quantification) by approximately 33 days following topical administration.
(S)-Methoprene and Amitraz: Dermal absorption is very low and all plasma concentrations were below the limit of quantification (10 ng/ml) for (S)-methoprene and were undetectable for amitraz (< 0.75 ng/ml) in most samples.

Distribution, metabolism, and excretion
Fipronil's major metabolite on the haircoat of the dog and in the blood stream is the sulfone derivative. Fipronil sulfone is produced on the haircoat (mean concentrations < 16 % of fipronil during the first month after treatment).
(S)-Methoprene is extensively degraded into carbon dioxide and acetate that are subsequently incorporated into endogenous materials.
Amitraz degrades on the haircoat of the dog into N-methyl-N'-(2,4-xylyl) formamidine (< 5 % of amitraz concentrations). Small concentrations of dimethylaniline, a minor degradation product of amitraz, were also observed on the haircoat of the dog post-application but in negligible quantities.

A pharmacokinetic study in dogs, of the active substances alone and in combination, showed that no drug interactions occur between the active substances that affect their pharmacokinetic parameters.

The three active substances are well distributed over the haircoat of the dog during the first week after application. The concentrations of fipronil, fipronil sulfone, amitraz and S-methoprene in the haircoat then decrease with time and are detectable for at least 58 days after dosing. Major metabolites are distributed over the entire haircoat of the dog. Fipronil sulfone decreased to concentrations of < 0.6 µg/g by 58 days after topical application. Low levels of N-methyl-N'-(2,4-xylyl) formamidine were detectable for 30 days after dosing.

Environmental properties

CERTIFECT should not enter water courses as this may be dangerous for fish and aquatic organisms.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole (E320)
Butylhydroxytoluene (E321)
Ethanol, anhydrous
Polysorbate 80 (E433)
Povidone
Diethylene glycol monoethyl ether
Octyl acetate

6.2 Incompatibilities

None known.

6.3 Shelf life

For the 1.07 ml pipette:
Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

For the 2.14 ml, 4.28 ml or 6.42 ml pipette:
Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Store in the original package.

6.5 Nature and composition of immediate packaging

Purple dual chamber pipette: The primary packaging is composed of two heat-formed polyolefin chambers with a central polyolefin-coated aluminium partition. The secondary packaging consists of a plastic/ aluminium blister with a plastic/ aluminium backing.

CERTIFECT spot-on solution	Volume of unit dose (ml)	card	carton box
dogs 2-10 kg	1.07	1 pipette	3 pipettes
dogs 10-20 kg	2.14	1 pipette	3 pipettes
dogs 20-40 kg	4.28	1 pipette	3 pipettes
dogs 40-60 kg	6.42	1 pipette	3 pipettes

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste material derived from it should be disposed of in accordance with local requirements and should not enter water courses as this may be dangerous for fish and aquatic organisms.

7. MARKETING AUTHORISATION HOLDER

MERIAL
29, avenue Tony Garnier
FR-69007 Lyon
France

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/125/001-008

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06/05/2011.
Date of latest renewal:

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

MERIAL
4, Chemin du Calquet
FR-31000 Toulouse Cedex
France

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box of 3 pipettes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CERTIFECT 67 mg/ 60.3 mg/ 80 mg spot-on solution for dogs 2-10 kg
CERTIFECT 134 mg/ 120.6 mg/ 160 mg spot-on solution for dogs 10-20 kg
CERTIFECT 268 mg/ 241.2 mg/ 320 mg spot-on solution for dogs 20-40 kg
CERTIFECT 402 mg/ 361.8 mg/ 480 mg spot-on solution for dogs 40-60 kg

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 1.07 ml of solution contains: Fipronil 67 mg, (S)-Methoprene 60.3 mg, Amitraz 80 mg
Each 2.14 ml of solution contains: Fipronil 134 mg, (S)-Methoprene 120.6 mg, Amitraz 160 mg
Each 4.28 ml of solution contains: Fipronil 268 mg, (S)-Methoprene 241.2 mg, Amitraz 320 mg
Each 6.42 ml of solution contains: Fipronil 402 mg, (S)-Methoprene 361.8 mg, Amitraz 480 mg

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

3 x 1.07 ml
3 x 2.14 ml
3 x 4.28 ml
3 x 6.42 ml

5. TARGET SPECIES

Dogs 2-10 kg
Dogs 10-20 kg
Dogs 20-40 kg
Dogs 40-60 kg

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

Spot-on use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use
For dog use only.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store in the original package.

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

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

For animal treatment only.
To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MERIAL
29, avenue Tony Garnier
FR-69007 Lyon
France.

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/125/005
EU/2/11/125/006
EU/2/11/125/007
EU/2/11/125/008

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Card of 1 pipette

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CERTIFECT 67 mg/ 60.3 mg/ 80 mg spot-on solution for dogs 2-10 kg
CERTIFECT 134 mg/ 120.6 mg/ 160 mg spot-on solution for dogs 10-20 kg
CERTIFECT 268 mg/ 241.2 mg/ 320 mg spot-on solution for dogs 20-40 kg
CERTIFECT 402 mg/ 361.8 mg/ 480 mg spot-on solution for dogs 40-60 kg

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 1.07 ml of solution contains: Fipronil 67 mg, (S)-Methoprene 60.3 mg, Amitraz 80 mg
Each 2.14 ml of solution contains: Fipronil 134 mg, (S)-Methoprene 120.6 mg, Amitraz 160 mg
Each 4.28 ml of solution contains: Fipronil 268 mg, (S)-Methoprene 241.2 mg, Amitraz 320 mg
Each 6.42 ml of solution contains: Fipronil 402 mg, (S)-Methoprene 361.8 mg, Amitraz 480 mg

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

1 x 1.07 ml
1 x 2.14 ml
1 x 4.28 ml
1 x 6.42 ml

5. TARGET SPECIES

Dogs 2-10 kg
Dogs 10-20 kg
Dogs 20-40 kg
Dogs 40-60 kg

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

Spot-on use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use
For dog use only.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store in the original package.

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

Read the package leaflet before use.

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

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHTAND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MERIAL
29, avenue Tony Garnier
FR-69007 Lyon
France.

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/125/001
EU/2/11/125/002
EU/2/11/125/003
EU/2/11/125/004

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

FOIL - For all pack sizes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CERTIFECT
1.07 ml
2.14 ml
4.28 ml
6.42 ml

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MERIAL

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

{number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING

PIPETTE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CERTIFECT

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

1.07 ml
2.14 ml
4.28 ml
6.42 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

{number}

7. EXPIRY DATE

{month/year}

8. NAME OF THE MARKETING AUTHORISATION HOLDER

MERIAL

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR
(Box of 3 pipettes)

CERTIFECT 67 mg/ 60.3 mg/ 80 mg spot-on solution for dogs 2-10 kg
CERTIFECT 134 mg/ 120.6 mg/ 160 mg spot-on solution for dogs 10-20 kg
CERTIFECT 268 mg/ 241.2 mg/ 320 mg spot-on solution for dogs 20-40 kg
CERTIFECT 402 mg/ 361.8 mg/ 480 mg spot-on solution for dogs 40-60 kg

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

Marketing authorisation holder:
MERIAL
29, avenue Tony Garnier
FR-69007 Lyon
France.

Manufacturer responsible for the batch release:
MERIAL
4, Chemin du Calquet
FR-31000 Toulouse Cedex
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

CERTIFECT 67 mg/ 60.3 mg/ 80 mg spot-on solution for dogs 2-10 kg
CERTIFECT 134 mg/ 120.6 mg/ 160 mg spot-on solution for dogs 10-20 kg
CERTIFECT 268 mg/ 241.2 mg/ 320 mg spot-on solution for dogs 20-40 kg
CERTIFECT 402 mg/ 361.8 mg/ 480 mg spot-on solution for dogs 40-60 kg

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Spot-on solution.
Clear amber to yellowish solution.

Each unit dose (dual cavity pipette) delivers:

CERTIFECT spot-on solution	Volume of unit dose (ml)	Fipronil (mg)	(S)-methoprene (mg)	Amitraz (mg)
dogs 2-10 kg	1.07	67.0	60.3	80.0
dogs 10-20 kg	2.14	134.0	120.6	160.0
dogs 20-40 kg	4.28	268.0	241.2	320.0
dogs 40-60 kg	6.42	402.0	361.8	480.0

Excipients essential for proper administration: butylhydroxyanisole (0.02 %) and butylhydroxytoluene (0.01 %).

4. INDICATIONS

Treatment and prevention of infestations in dogs by ticks (*Ixodes ricinus, Dermacentor reticulatus, Rhipicephalus sanguineus, Ixodes scapularis, Dermacentor variabilis, Haemaphysalis elliptica, Haemaphysalis longicornis, Amblyomma americanum* and *Amblyomma maculatum)* and fleas *(Ctenocephalides felis* and *Ctenocephalides canis).*

Treatment of infestations by chewing lice (*Trichodectes canis*).

Prevention of environmental flea contamination by inhibiting the development of all flea immature stages.
The product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).

Elimination of fleas and ticks within 24 hours. One treatment prevents further infestations for 5 weeks by ticks and for up to 5 weeks by fleas.
The treatment indirectly reduces the risk of transmission of tick-borne diseases (canine babesiosis, monocytic ehrlichiosis, granulocytic anaplasmosis and borreliosis) from infected ticks for 4 weeks.

5. CONTRAINDICATIONS

Do not use on sick (e.g. systemic diseases, diabetes, fever) or convalescent animals.
Do not use in rabbits and cats.

6. ADVERSE REACTIONS

Transient skin reactions at the application site (skin discolouration, local hair loss, itching, redness) and general itching or hair loss may occur on rare occasions. Lethargy, ataxia, emesis, anorexia, diarrhoea, excessive salivation, hyperglycaemia, increased sensitivity to stimulation, bradycardia or bradypnea may be observed. Signs are transitory and generally resolve without treatment within 24 hours.

In very rare instances, certain sensitive dogs may develop skin irritation at the application site. Other forms of dermatitis including pemphigus-like conditions may occur in even rarer instances. Should this occur, contact your veterinarian promptly for treatment advice and discontinue use of the product.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

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

Dosage:
The recommended minimum dose is 6.7 mg/kg bodyweight (b.w.) for fipronil, 6 mg/kg for (S)-methoprene and 8 mg/kg for amitraz.

Spot-on use

Treatment schedule:
Monthly intervals throughout the tick and/or flea seasons, based on local epidemiological situations.

9. ADVICE ON CORRECT ADMINISTRATION

1. Separate one blister from the others by tearing along perforation.
2. Use a pair of scissors to cut the blister along the dotted line (or fold on the corner as shown and pull the foil away).
3. Remove the pipette and hold it upright. Cut off the pipette tip with a pair of scissors.
4. Part the coat until the skin is visible. Place the tip of the pipette on the skin. Squeeze pipette, apply about half of the contents half way down the neck between the base of the skull and the shoulder blades. Repeat the application at the base of the neck in front of the shoulder blades to empty pipette.
5. Apply onto dry skin where the animal cannot lick it off and make sure that animals do not lick each other following treatment.

CERTIFECT treatment causes detachment of ticks when applied to a dog with a pre-existing infestation, disrupts attachment and rapidly kills ticks within 24 hours thus inhibiting the blood meal and the concomitant risk of transmission of tick-borne pathogens. The risk of developing canine babesiosis, monocytic ehrlichiosis, granulocytic anaplasmosis and borreliosis for 4 weeks is thereby indirectly reduced.

Remains effective after exposure to sunlight or if the animal becomes wet after rain, bathing, or water immersion. However, shampooing or immersion of the animal in water directly after treatment or frequent shampooing may reduce the duration of activity. Treated animals should not be bathed until 48 hours after treatment. If the dog requires shampooing, it is better to do so before applying the veterinary medicinal product.

All stages of fleas can infest the dog's basket, bedding and regular resting areas such as carpets and soft furnishings. In case of massive flea infestation and at the beginning of the control measures these areas should be treated with a suitable environmental product and then vacuumed regularly.
After treatment with CERTIFECT, ticks will generally be killed and fall off the dog within 24 hours after infestation without having a blood meal. However the attachment of single ticks after treatment cannot be excluded. For this reason the transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in the original package.

Do not use after the expiry date stated on the outer package after EXP.

12. SPECIAL WARNINGS

Special precautions for use in animals:
Avoid contact with the dog's eyes.
For spot-on application only. Do not administer orally or via any other route.
The treated area may appear wet or oily after treatment.
In the absence of additional safety studies, do not repeat the treatment at intervals of less than 2weeks, do not treat puppies less than 8 weeks of age and dogs less than 2 kg bodyweight.
Dogs should be prevented from accessing streams and rivers for 48-hours following treatment.

Known side-effects of amitraz and its metabolites are due to alpha-2-adreno-receptor agonist effects. They may consist of hypersalivation, vomiting, lethargy, hyperglycaemia, bradycardia or bradypnea. Signs are transitory and generally resolve without treatment within 24 hours.
If symptoms are severe or persist alternatively use antidote (atipamezole hydrochloride).
The risk of experiencing adverse reactions may increase with overdosing, so animals should always be treated with the correct pipette size adapted to the body weight.

This veterinary medicinal product contains amitraz, which is a monoamine oxidase inhibitor (MAOI); therefore, in the absence of studies, this veterinary medicinal product should not be used on dogs treated with MAOI.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product may cause skin sensitisation, allergic reactions and mild eye irritation in humans. Animals or persons with a known hypersensitivity to any of the active ingredients or excipients should avoid contact which, on very rare occasions, can cause respiratory irritation and dermal reactions in certain individuals. The use of protective gloves is recommended.
Avoid direct contact with the application site. Children should not be allowed to play with treated dogs until the application site is dry. It is therefore recommended that dogs are not treated during the day, but during the early evening, and that recently treated animals are not allowed to sleep with owners, especially children.
This veterinary medicinal product contains amitraz, which can lead to neurological side-effects in humans.
Amitraz is a monoamine oxidase inhibitor (MAOI); therefore, people taking MAOI-containing medication should take particular care and avoid direct contact with the product.
To minimise the potential for inhalation, apply in the open air or in a well ventilated area.
Do not smoke, drink or eat whilst handling.
Wash hands thoroughly after use.
Used pipettes should be disposed of immediately. Stored pipettes must be kept in the intact foil package.
In case of accidental spillage onto skin, wash off immediately with soap and water. If its accidentally gets into the eyes, they should be thoroughly flushed with water.
In case of incorrect use, seek medical advice immediately and show the package leaflet or the label to the physician.
If side effects are noted, seek immediate medical assistance and show the package leaflet or label to the physician.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Overdose:
Safety was demonstrated in breeding, pregnant and lactating animals treated at 28-day intervals with multiple consecutive doses up to 3 times the maximum recommended dose.Safety has been also demonstrated with up to 5 times the recommended dose in healthy adult dogs (treated up to 6 times at two-week intervals) and in puppies (aged 8 weeks treated once).

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

Medicines should not be disposed of via wastewater or household waste.
Any unused veterinary medicinal product or waste materials derived from it should be disposed of in accordance with local requirements and should not enter water courses as this may be dangerous for fish and aquatic organisms.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

15. OTHER INFORMATION

Each strength of the veterinary medicinal product is available in cards with 1 pipette and in carton boxes of 3 pipettes.
Not all pack sizes may be marketed.
For animal treatment only.
To be supplied only on veterinary prescription.

PACKAGE LEAFLET FOR
(Card of 1 pipette)

CERTIFECT 67 mg/ 60.3 mg/ 80 mg spot-on solution for dogs 2-10 kg
CERTIFECT 134 mg/ 120.6 mg/ 160 mg spot-on solution for dogs 10-20 kg
CERTIFECT 268 mg/ 241.2 mg/ 320 mg spot-on solution for dogs 20-40 kg
CERTIFECT 402 mg/ 361.8 mg/ 480 mg spot-on solution for dogs 40-60 kg

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

Marketing authorisation holder
MERIAL
29, avenue Tony Garnier
FR-69007 Lyon
France.

Manufacturer responsible for the batch release:
MERIAL
4, Chemin du Calquet
FR-31000 Toulouse Cedex
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

CERTIFECT 67 mg/ 60.3 mg/ 80 mg spot-on solution for dogs 2-10 kg
CERTIFECT 134 mg/ 120.6 mg/ 160 mg spot-on solution for dogs 10-20 kg
CERTIFECT 268 mg/ 241.2 mg/ 320 mg spot-on solution for dogs 20-40 kg
CERTIFECT 402 mg/ 361.8 mg/ 480 mg spot-on solution for dogs 40-60 kg

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Spot-on solution.
Clear amber to yellowish solution.

Each unit dose (dual cavity pipette) delivers:

CERTIFECT spot-on solution	Volume of unit dose (ml)	Fipronil (mg)	(S)-methoprene (mg)	Amitraz (mg)
dogs 2-10 kg	1.07	67.0	60.3	80.0
dogs 10-20 kg	2.14	134.0	120.6	160.0
dogs 20-40 kg	4.28	268.0	241.2	320.0
dogs 40-60 kg	6.42	402.0	361.8	480.0

Excipients essential for proper administration: butylhydroxyanisole (0.02 %) and butylhydroxytoluene (0.01 %).

4. INDICATIONS

Treatment and prevention of infestations in dogs by ticks (*Ixodes ricinus, Dermacentor reticulatus, Rhipicephalus sanguineus, Ixodes scapularis, Dermacentor variabilis, Haemaphysalis elliptica, Haemaphysalis longicornis, Amblyomma americanum* and *Amblyomma maculatum)* and fleas *(Ctenocephalides felis* and *Ctenocephalides canis).*

Treatment of infestations by chewing lice (*Trichodectes canis*).

Prevention of environmental flea contamination by inhibiting the development of all flea immature stages.

The product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).

Elimination of fleas and ticks within 24 hours. One treatment prevents further infestations for 5 weeks by ticks and for up to 5 weeks by fleas.
The treatment indirectly reduces the risk of transmission of tick-borne diseases (canine babesiosis, monocytic ehrlichiosis, granulocytic anaplasmosis and borreliosis) from infected ticks for 4 weeks.

5. CONTRAINDICATIONS

Do not use on sick (e.g. systemic diseases, diabetes, fever) or convalescent animals.
Do not use in rabbits and cats.

6. ADVERSE REACTIONS

Transient skin reactions at the application site (skin discolouration, local hair loss, itching, redness) and general itching or hair loss may occur on rare occasions. Lethargy, ataxia, emesis, anorexia, diarrhoea, excessive salivation, hyperglycaemia, increased sensitivity to stimulation, bradycardia or bradypnea may be observed. Signs are transitory and generally resolve without treatment within 24 hours.

In very rare instances, certain sensitive dogs may develop skin irritation at the application site. Other forms of dermatitis including pemphigus-like conditions may occur in even rarer instances. Should this occur, contact your veterinarian promptly for treatment advice and discontinue use of the product.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

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

Dosage:
The recommended minimum dose is 6.7 mg/kg bodyweight (b.w.) for fipronil, 6 mg/kg for (S)-methoprene and 8 mg/kg for amitraz.

Spot-on use

Treatment schedule:
Monthly intervals throughout the tick and/or flea seasons, based on local epidemiological situations.

9. ADVICE ON CORRECT ADMINISTRATION

1. Use a pair of scissors to cut the blister along the dotted line (or fold the blister on the corner as shown, and pull the foil away).
2. Remove the pipette and hold it upright. Cut off the pipette tip with a pair of scissors.
3. Part the coat until the skin is visible. Place the tip of the pipette on the skin. Squeeze pipette, apply about half of the contents half way down the neck between the base of the skull and the shoulder blades. Repeat the application at the base of the neck in front of the shoulder blades to empty pipette.
4. Apply onto dry skin where the animal cannot lick it off and make sure that animals do not lick each other following treatment.

CERTIFECT treatment causes detachment of ticks when applied to a dog with a pre-existing infestation, disrupts attachment and rapidly kills ticks within 24 hours thus inhibiting the blood meal and the concomitant risk of transmission of tick-borne pathogens. The risk of developing canine babesiosis, monocytic ehrlichiosis, granulocytic anaplasmosis and borreliosis for 4 weeks is thereby indirectly reduced.

Remains effective after exposure to sunlight or if the animal becomes wet after rain, bathing, or water immersion. However, shampooing or immersion of the animal in water directly after treatment or frequent shampooing may reduce the duration of activity. Treated animals should not be bathed until 48 hours after treatment. If the dog requires shampooing, it is better to do so before applying the veterinary medicinal product.

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ANNEX IV

GROUNDS FOR ONE ADDITIONAL RENEWAL

The CVMP at their meeting on 18 February 2016 decided that one additional five-year renewal was required in view of the outstanding pharmacovigilance data that were undergoing evaluation at the time of the renewal procedure and to ensure that the MAH's pharmacovigilance system is adequate to enable collection and evaluation of adverse events in line with the requirements.