SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprodog 134 mg spot-on solution for medium dogs (DE, NL, GR, CY)
Fiprodog Biocanina 134 mg spot-on solution for medium dogs (FR, RO)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1.34 ml pipette contains:

Active substances:
Fipronil ..... 134.00 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 (E 320)	0.268 mg
Butylhydroxytoluene (E 321)	0.134 mg
Diethylene glycol monoethyl ether	

Spot-on solution
Clear, colourless to yellowish solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs (10-20 kg)

3.2 Indications for use for each target species

For the treatment against flea infestations (*Ctenocephalides spp.*)
Insecticidal efficacy against new infestation with fleas persists for up to 6 weeks.

The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD), where this has been previously diagnosed by a veterinary surgeon.

Although the product does not consistently show an immediate acaricidal efficacy (several ticks may be present after 48 hours), it has a persistent acaricidal efficacy for up to 4 weeks against *Dermacentor variabilis* and up to 3 weeks against *Rhipicephalus sanguineus*.

3.3 Contraindications

Do not use on puppies less than 2 months old and/or weighing less than 2 kg in the absence of available data.
Do not use on sick (systemic disease, fever, etc.) or convalescent animals.
Do not use on rabbits, as adverse drug reactions and even death could occur.
This veterinary medicinal product has been developed specifically for dogs. Do not use on cats as this could lead to overdosing.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

The veterinary medicinal product does not prevent an infestation of the animal by ticks.

Ticks will usually die within 48 hours of infestation, however attached ticks (both live and killed) may be seen at this time. Some of these will have had a blood meal.

Death normally occurs before the ticks are fully engorged so that the risk of transmission of infectious diseases by ticks is minimised, but cannot be completely ruled out. As soon as the ticks are dead they generally fall off the animal; remaining ticks can be removed with a gentle pull.

For the optimal control of flea problems in households with several animals all dogs and cats should be treated with an authorised insecticide.

Fleas from pets often infest animal's baskets, 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.

Shampooing with a medicated shampoo, followed by thorough drying, 1 to 2 hours before treatment application and bathing once weekly over a period of 6 weeks, has been shown not to affect the efficacy of this veterinary medicinal product against fleas. Bathing and intensive wetting of the coat should be avoided for the first 2 days following administration of the veterinary medicinal product.

When used as part of a strategy for the treatment of Flea Allergy Dermatitis, monthly applications to the allergic patients and to other animals in the household are recommended.

3.5 Special precautions for use

Special precautions for safe use in the target species:
This veterinary medicinal product should not be used on dogs weighing less than 10 kg.
It is important to make sure that the veterinary medicinal product is applied to an area where the animal cannot lick it off. Do not allow recently treated animals to lick each other. If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier substance.
Avoid contact with the animal's eyes. Should the veterinary medicinal product come into contact with the eyes, rinse thoroughly at once with water.
Do not apply the veterinary medicinal product to wounds or skin lesions.
There may be an attachment of some ticks. For this reason, transmission of infectious diseases cannot be excluded if conditions are unfavourable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product can cause mucous membrane and eye irritation. Therefore, contact between the veterinary medicinal product and the mouth or eyes should be avoided.
In the case of accidental eye contact 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 contents coming into contact with the fingers. If this occurs, wash off immediately with soap and water.
Wash hands after use.
Do not smoke, drink or eat during application.
People with a known hypersensitivity to fipronil or other excipients should avoid contact with the veterinary medicinal product.
Treated animals should not be handled until the application site is dry, and children should not be allowed to play with treated animals until the application site is dry. It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals should not be allowed to sleep with owners, especially children.
Keep pipettes in the original packaging and dispose of used pipettes immediately.

Special precautions for the protection of the environment:
Dogs should not be allowed to swim in watercourses for 2 days after application (see section 5.5).

Other precautions
The veterinary medicinal product may have adverse effects on painted, varnished or other household surfaces or furnishings.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site reactions[1]: application site skin scaling, application site alopecia, application site pruritus, application site erythema Pruritus[2] Alopecia[2] Hypersalivation, Vomiting Neurological signs[3]: hyperesthesia, central nervous system depression, nervousness Respiratory signs

[1]transient
[2]general
[3]reversible

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:
Laboratory studies using fipronil have not produced any evidence of teratogenic or embryotoxic effects. Studies have not been carried out with this veterinary medicinal product in pregnant and lactating bitches. 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 use. External use only.
1 pipette of 1.34 ml is sufficient for the treatment of a dog with a body weight of 10 kg up to 20 kg corresponding to a recommended minimum dose of 6.7 mg fipronil/kg body weight.

To ensure a correct dosage, body weight should be determined as accurately as possible.
The minimum interval between two treatments should be not less than 4 weeks.

Advice for the safe application:
Disconnect one of the blisters from the blister card. This helps to avoid accidental opening of the adjacent blister package in order to protect the still unopened pipettes from exposure to humidity. Open the blister with scissors. To avoid damaging of the pipette cut along the line marked with the scissors icon. Carefully peel back the foil from the cut off end and withdraw the pipette.

Hold the pipette upright. Tap lightly to ensure the entire liquid contents are within the main body of the pipette. Bend the upper border strip backwards. Then the pipette can be set aside, if necessary. To open the pipette snap off the top of the pipette along the scored line.

Part the coat between 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 content completely and directly onto the skin in one spot.

Application of the solution near the base of the head minimises the possibility that the animal will lick the solution off. Care should be taken after the application that animals do not mutually lick off the solution.
Care should be taken to avoid excessive wetting of the hair with the veterinary medicinal product since this will cause a sticky appearance of hairs at the treatment spot.
However should this occur, it will disappear within 24 hours post application.

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

The toxicity of the veterinary medicinal product administered to the skin is very low. The risk of experiencing adverse effects (see section 3.6) may however increase when overdosing, so animals should always be treated with the correct pipette size according to body weight.

Specific studies investigating the safety of the veterinary medicinal product following repeated administration or at over dosage have not been conducted due to the known safety profile of the active substance and excipients.

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: QP53AX15

4.2 Pharmacodynamics

Fipronil belongs to the group of phenylpyrazoles. It acts by inhibiting the GABA complex, binding to the chloride channel thereby blocking pre- and post-synaptic transfer of chloride ions across the membrane. This results in uncontrolled activity of the central nervous system and hence to death in insects.
Fipronil acts as an insecticide against fleas (*Ctenocephalides spp.*) and as an acaricide against ticks (*Rhipicephalus sanguineus* and *Dermacentor variabilis*).
Fleas are killed within 48 hours. Most ticks are killed within 48 hours. Some ticks may still be present after 48 hours.

4.3 Pharmacokinetics

The veterinary medicinal product distributes itself within 48 hours over the entire skin of the animal.
The absorption of fipronil is negligible in dogs following topical application.
The concentration of fipronil on the fur decreases over time.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 4 years

5.3 Special precautions for storage

Store in the original package.
This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Pipettes containing an extractable volume of 1.34 ml.

The pipettes are made of:
- bottom foil: polyethylene terephthalate/polypropylene
- lidding foil: polyethylene terephthalate/aluminium

To protect the content of the pipettes from moisture and light the pipettes are individually packed in blister foils made of:
- cold-form foil for blister: polyvinyl chloride/(biaxially) oriented polymide/aluminium/polyvinyl chloride
- lidding foil for blister: polyethylene terephthalate/aluminium

A blister card consists of 3 blisters, each containing a single pipette.
Cardboard packs containing 3, 6, 12, 24, 60 and 120 pipettes

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

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

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.

Fipronil may be harmful to aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

DOMES PHARMA

7. MARKETING AUTHORISATION NUMBER(S)

CY : CY00313V
DE: 401305.02.00
EL: 30445 /23-03-2022
FR: FR/V/7459897 7/2010
NL: REG NL 106394
RO: 220044

8. DATE OF FIRST AUTHORISATION

CY : 28/06/2011
DE: 17/12/2010
EL: 23/11/2011
FR: 20/12/2010
NL: 18/01/2011
RO: 04/07/2011

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

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

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprodog 134 mg spot-on solution (DE, NL, GR, CY)
Fiprodog Biocanina 134 mg spot-on solution (FR, RO)

External antiparasitic

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1.34 ml pipette contains:
Fipronil ..... 134.00 mg

3. PACKAGE SIZE

3 pipettes
6 pipettes
12 pipettes
24 pipettes
60 pipettes
120 pipettes

4. TARGET SPECIES

Dogs (10 - 20 kg)

5. INDICATIONS

Against fleas and ticks.

6. ROUTES OF ADMINISTRATION

Spot-on use. External use only.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

EXP {month/year}

9. SPECIAL STORAGE PRECAUTIONS

Store in the original package.

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

DOMES PHARMA

14. MARKETING AUTHORISATION NUMBERS

CY : CY00313V
DE: 401305.02.00
EL: 30445 /23-03-2022
FR: FR/V/7459897 7/2010
NL: REG NL 106394
RO: 220044

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprodog (DE, NL, GR, CY)
Fiprodog Biocanina (FR, RO)

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Fipronil 134 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {month/year}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{pipette}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprodog (DE, NL, GR, CY)
Fiprodog Biocanina (FR, RO)

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Fipronil 134 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {month/year}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Fiprodog 134 mg spot-on solution for medium dogs (DE, NL, GR, CY)
Fiprodog Biocanina 134 mg spot-on solution for medium dogs (FR, RO)

2. Composition

Each 1.34 ml pipette contains:
Fipronil ..... 134.00 mg
Butylhydroxyanisole (E 320) …… 0.268 mg
Butylhydroxytoluene (E 321) …… 0.134 mg

Clear, colourless to yellowish solution.

3. Target species

Dogs (10 – 20 kg)

4. Indications for use

For the treatment against flea infestations (*Ctenocephalides spp.*)
Insecticidal efficacy against new infestation with fleas persists for up to 6 weeks.

The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD), where this has been previously diagnosed by a veterinary surgeon.

Although the product does not consistently show an immediate acaricidal efficacy (several ticks may be present after 48 hours), it has a persistent acaricidal efficacy for up to 4 weeks against *Dermacentor variabilis* and up to 3 weeks against *Rhipicephalus sanguineus*.

5. Contraindications

Do not use on puppies less than 2 months old and/or weighing less than 2 kg in the absence of available data.
Do not use on sick (systemic disease, fever, etc.) or convalescent animals.
Do not use on rabbits, as adverse drug reactions and even death could occur.
This veterinary medicinal product has been developed specifically for dogs. Do not use on cats as this could lead to overdosing.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:
The veterinary medicinal product does not prevent an infestation of the animal by ticks.
Ticks will usually die within 48 hours of infestation, however attached ticks (both live and killed) may be seen at this time. Some of these will have had a blood meal.

Death normally occurs before the ticks are fully engorged so that the risk of transmission of infectious diseases by ticks is minimised, but cannot be completely ruled out. As soon as the ticks are dead they generally fall off the animal; remaining ticks can be removed with a gentle pull.

For the optimal control of flea problems in households with several animals all dogs and cats should be treated with an authorised insecticide.

Fleas from pets often infest animal's baskets, 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.

Shampooing with a medicated shampoo, followed by thorough drying, 1 to 2 hours before treatment application and bathing once weekly over a period of 6 weeks, has been shown not to affect the efficacy of this veterinary medicinal product against fleas. Bathing and intensive wetting of the coat should be avoided for the first 2 days following administration of the veterinary medicinal product.

When used as part of a strategy for the treatment of Flea Allergy Dermatitis, monthly applications to the allergic patients and to other animals in the household are recommended.

Special precautions for safe use in the target species:
This veterinary medicinal product should not be used on dogs weighing less than 10 kg.
It is important to make sure that the veterinary medicinal product is applied to an area where the animal cannot lick it off. Do not allow recently treated animals to lick each other. If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier substance.
Avoid contact with the animal's eyes. Should the veterinary medicinal product come into contact with the eyes, rinse thoroughly at once with water.
Do not apply the veterinary medicinal product to wounds or skin lesions.
There may be an attachment of some ticks. For this reason, transmission of infectious diseases cannot be excluded if conditions are unfavourable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product can cause mucous membrane and eye irritation. Therefore, contact between the veterinary medicinal product and the mouth or eyes should be avoided.
In the case of accidental eye contact 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 contents coming into contact with the fingers. If this occurs, wash off immediately with soap and water.
Wash hands after use.
Do not smoke, drink or eat during application.
People with a known hypersensitivity to fipronil or other excipients should avoid contact with the veterinary medicinal product.
Treated animals should not be handled until the application site is dry, and children should not be allowed to play with treated animals until the application site is dry. It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals should not be allowed to sleep with owners, especially children.
Keep pipettes in the original packaging and dispose of used pipettes immediately.

Special precautions for the protection of the environment:
Dogs should not be allowed to swim in watercourses for 2 days after application (see section “Special precautions for disposal”).

Other precautions:
The veterinary medicinal product may have adverse effects on painted, varnished or other household surfaces or furnishings.

Pregnancy and lactation:
Laboratory studies using fipronil have not produced any evidence of teratogenic or embryotoxic effects. Studies have not been carried out with this veterinary medicinal product in pregnant and lactating bitches. Use only according to the benefit-risk assessment by the responsible veterinarian.

Overdose:

The toxicity of the veterinary medicinal product administered to the skin is very low. The risk of experiencing adverse effects (see section “Adverse events”) may however increase when overdosing, so animals should always be treated with the correct pipette size according to body weight.

Specific studies investigating the safety of the veterinary medicinal product following repeated administration or at over dosage have not been conducted due to the known safety profile of the active substance and excipients.

7. Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Application site reactions[1]: application site skin scaling, application site alopecia, application site pruritus, application site erythema
Pruritus[2]
Alopecia[2]
Hypersalivation, Vomiting
Neurological signs[3]: hyperesthesia, central nervous system depression, nervousness
Respiratory signs
[1]transient
[2]general
[3]reversible

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 either the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system:{national system details}.

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

Spot-on use. External use only.
1 pipette of 1.34 ml is sufficient for the treatment of a dog with a body weight of 10 kg up to 20 kg corresponding to a recommended minimum dose of 6.7 mg fipronil/kg body weight.

To ensure a correct dosage, body weight should be determined as accurately as possible.
The minimum interval between two treatments should be not less than 4 weeks.

9. Advice on correct administration

Disconnect one of the blisters from the blister card. This helps to avoid accidental opening of the adjacent blister package in order to protect the still unopened pipettes from exposure to humidity.
Open the blister with scissors. To avoid damaging of the pipette cut along the line marked with the scissors icon. Carefully peel back the foil from the cut off end and withdraw the pipette.
Hold the pipette upright. Tap lightly to ensure the entire liquid contents are within the main body of the pipette. Bend the upper border strip backwards. Then the pipette can be set aside, if necessary. To open the pipette snap off the top of the pipette along the scored line.

Part the coat between 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 content completely and directly onto the skin in one spot.

Application of the solution near the base of the head minimises the possibility that the animal will lick the solution off. Care should be taken after the application that animals do not mutually lick off the solution.
Care should be taken to avoid excessive wetting of the hair with the veterinary medicinal product since this will cause a sticky appearance of hairs at the treatment spot.
However should this occur, it will disappear within 24 hours post application.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Store in the original package.
This veterinary medicinal product does not require any special storage conditions.

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

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
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.
Fipronil may be harmful to aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation numbers:
CY : CY00312V
DE: 401305.02.00
EL: 30444 /23-03-2022
FR: FR/V/8275562 9/2010
NL: REG NL 106393
RO: 220044

Pack sizes:
Pipettes containing an extractable volume of 1.34 ml.
A blister card consists of 3 blisters, each containing a single pipette.
Cardboard packs containing 3, 6, 12, 24, 60 and 120 pipettes
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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
DOMES PHARMA
3 rue André Citroën
63430 Pont-du-Château
France

Manufacturer responsible for batch release:
KLOCKE VERPACKUNGS - SERVICE GmbH
Max-Becker-Str.6
76356 Weingarten
Germany

Local representatives and contact details to report suspected adverse events: