PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet {Box of 1 pipette (or 3 pipettes or 4 pipettes or 6 pipettes}

CASE N°1: The text below corresponds to the cases where all the information of the package leaflet CAN be conveyed on the outer packaging and container. Consequently, in that case, no separate leaflet is provided in compliance with the current QRD Template.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTLINE PLUS SPOT-ON DOG S

2. COMPOSITION

Each 0.67 ml pipette contains:

Active substances:
Fipronil.....67.00 mg
(S)-methoprene .....60.30 mg
Excipients:
Butylhydroxyanisole (E320).....0.13 mg
Butylhydroxytoluene (E321) .....0.07 mg

FIPRONIL 10% w/v (S) METHOPRENE 9% w/v
[Where there is sufficient space, 'w/v' will be added after the percentages of the active substances. Where there is a lack of space, an asterisk will be added next to the percentages with an explanatory note placed close to the Veterinary Medicinal Product name.]

Clear amber spot-on solution.

3. PACKAGE SIZE

1 pipette of 0.67 ml
3 pipettes of 0.67 ml
4 pipettes of 0.67 ml
6 pipettes of 0.67 ml

4. TARGET SPECIES

Dogs

5. INDICATIONS FOR USE

Indications for use

For the treatment of dogs weighing 2-to-10 kg bodyweight.

The treatment and prevention of flea and tick infestations and/or biting lice.
- Treatment of flea infestations (*Ctenocephalides* spp.). Insecticidal efficacy against new infestations with adult fleas persists for 8 weeks. Prevention of the multiplication

of fleas for 8 weeks after application by killing flea eggs (ovicidal activity) and larvae (larvicidal activity). By killing the larvae, pupae are prevented from developing.
- Treatment of tick infestations (*Ixodes ricinus*, *Dermacentor variabilis*, *Dermacentor reticulatus*, *Rhipicephalus sanguineus*). The veterinary medicinal product has a persistent acaricidal efficacy for up to 4 weeks against ticks.
- Treatment of infestations with biting lice (*Trichodectes canis*).

6. CONTRAINDICATIONS

Contraindications

In the absence of available data, the veterinary medicinal product should not be used on puppies less than 8 weeks old and/or weighing less than 2 kg.
Do not use on rabbits, as adverse events and even death could occur. In absence of studies, the use of the veterinary medicinal product is not recommended in non-target species.
Do not use on sick (e.g. systemic diseases, fever) or convalescent animals.
This veterinary medicinal product is specifically developed for dogs. Do not use in cats and ferrets, as this could lead to overdosing.
In the absence of safety studies, the minimum treatment interval is 4 weeks.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

7. SPECIAL WARNINGS

Special warnings

Bathing/immersion in water within 2 days after application of the veterinary medicinal product and more frequent bathing than once a week should be avoided, as no study has been performed to investigate how this affects the efficacy of the veterinary medicinal product. Emollient shampoos can be used prior to treatment but reduce the duration of protection against fleas to approximately 5 weeks when used weekly after application of the veterinary medicinal product. Weekly bathing with a 2% chlorhexidine medicated shampoo did not affect efficacy against fleas during a 6 week long study.

There may be an attachment of a few ticks. For this reason, a transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.

In case of infestation, carpets and non-washable furnishings should be treated with an appropriate insecticide household spray to kill eggs and larvae already in the home. Wash all pet bedding at 60°C as fleas often infest the animal's regular resting areas. Vacuum the whole house, including under furniture.

Other pets living in the same household should also be treated with a suitable veterinary medicinal product.

<u>Special precautions for safe use in the target species:</u>
For external use only.
Avoid contact with the animal's eyes.

It is important to make sure that the veterinary medicinal product is applied to an area where the animal cannot lick it off and to make sure that animals do not groom each other following treatment until the application site is dry.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Keep pipettes in original packaging until ready to use. In order to prevent children from getting access to used pipettes, dispose of used pipettes immediately.
This veterinary medicinal product can cause mucous membrane, skin and eye irritation. Therefore, contact of the veterinary medicinal product with mouth, skin and eyes should be avoided.
In the event of accidental exposure to the eye, it should be rinsed carefully with water.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

People with a known hypersensitivity (allergy) to insecticides, such as Fipronil or (S)-methoprene, or to alcohol should avoid contact with this veterinary medicinal product.
Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.

Wash hands after use.

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 are not allowed to sleep with owners, especially children.

Do not smoke, drink or eat during application.

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 alcohol carrier may have adverse effects on painted, varnished or other household surfaces or furnishings.

Pregnancy and lactation:
The veterinary medicinal product can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Do not use simultaneously with other flea products which are applied directly on to the animal.

Overdose:
Do not overdose.

The risk of experiencing adverse effects may increase when overdosing (see section 8 “Adverse Events”), so dogs should always be treated with the correct pipette size according to bodyweight.
No adverse events were observed in target animal safety studies in 8 week-old puppies, growing dogs and dogs weighing about 2 kg treated once at 5 times the recommended dose.

8. ADVERSE EVENTS

Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Application site reactions (skin discoloration[1], localised hair loss[1], itching[1], reddening[1]).
Generalised itching or hair loss. Hypersalivation[2], vomiting, respiratory signs.
Increased sensitivity to stimulation[3], depression[3], other nervous signs[3].

[1] Transient.
[2] If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.
[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 the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details on this label, or via your national reporting system:
Website: www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

Spot-on

Dogs should be weighed accurately prior to treatment.

One pipette of 0.67 ml (S) per dog weighing over 2 and up to 10 kg, corresponding to a minimum recommended dose of 6.7 mg/kg for fipronil and 6 mg/kg for (S)-methoprene, by topical application to the skin.

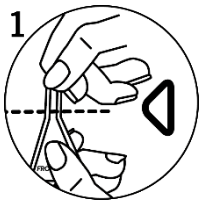
In the absence of safety studies, the minimum treatment interval is 4 weeks.

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

10. ADVICE ON CORRECT ADMINISTRATION

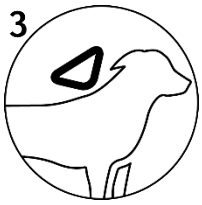
Advice on correct administration

METHOD OF ADMINISTRATION
1- Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette. Snap back the tip.



2 -Part the coat on the back of the animal at the base of the neck in front of the shoulder blades until the skin is visible.

3- Place the tip of the pipette on the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin in one spot.



Temporary changes to the coat (clumped/greasy hair) may be noted at the application site.

11. WITHDRAWAL PERIODS

Withdrawal periods: not applicable.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.
Do not store above 30°C. Store in the original packaging. Store in a dry place.
Flammable.

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

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater.

The veterinary medicinal product should not enter water courses as fipronil and (S)-methoprene may be dangerous for fish and other aquatic organisms. Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or empty containers.

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.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription.

15. MARKETING AUTHORISATION NUMBER AND PACK SIZES

Vm 61700/3074

Pack sizes

Blister card of 1 x 0.67 ml pipette
Box of 1 blister card of 1 x 0.67 ml pipette
Box of 1 blister card of 1 x 0.67 ml pipette and two empty blister spaces
Box of 1 blister card of 3 x 0.67 ml pipettes
Box of 1 blister card of 4 x 0.67 ml pipettes
Box of 2 blister cards of 3 x 0.67 ml pipettes

Not all pack sizes may be marketed.

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany
petsUK@boehringer-ingelheim.com
Tel: +353 1 291 3985

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS
4 chemin du Calquet
31000 Toulouse, France

<Local representatives:>

18. OTHER INFORMATION

Other information

AVM-GSL

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

21. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{FRONTLINE PLUS SPOT-ON DOG S Box of 1 pipette (or 3 pipettes or 4 pipettes or 6 pipettes)}

CASE N°2: *The text below corresponds to the cases where all the information of the package leaflet can not be conveyed on the outer packaging and the container* ***(for example for multilingual packaging****). Consequently a package leaflet is added (see the corresponding template).*

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTLINE PLUS SPOT-ON DOG S

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.67 ml pipette contains:
Fipronil.....67.00 mg
(S)-methoprene .....60.30 mg

FIPRONIL 10% w/v (S) METHOPRENE 9% w/v
[Where there is sufficient space, 'w/v' will be added after the percentages of the active substances. Where there is a lack of space, an asterisk will be added next to the percentages with an explanatory note placed close to the Veterinary Medicinal Product name.]

Clear amber spot-on solution.

3. PACKAGE SIZE

1 pipette of 0.67 ml
3 pipettes of 0.67 ml
4 pipettes of 0.67 ml
6 pipettes of 0.67 ml

4. TARGET SPECIES

Dogs 2 - 10 kg

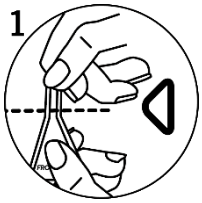
5. INDICATIONS

Read the package leaflet before use.
[More information is provided in the package leaflet. See the corresponding template.]

6. ROUTES OF ADMINISTRATION

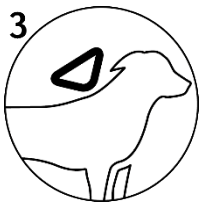
Spot-on

METHOD OF ADMINISTRATION
1- Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette. Snap back the tip.



2-Part the coat on the back of the animal at the base of the neck in front of the shoulder blades until the skin is visible.

3-Place the tip of the pipette on the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin in one spot.



Temporary changes to the coat (clumped/greasy hair) may be noted at the application site.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C. Store in the original packaging.
Store in a dry place. Flammable.

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 HOLDERS

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 61700/3074

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{FRONTLINE PLUS SPOT-ON DOG S Blister card of 1 pipette}

The information mentioned below is all the information visible externally on this packaging, either on the blister card or on the combined label package-leaflet inserted in it.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTLINE PLUS SPOT-ON DOG S

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.67 ml pipette contains:
Fipronil.....67.00 mg
(S)-methoprene .....60.30 mg

FIPRONIL 10% w/v (S) METHOPRENE 9% w/v
[Where there is sufficient space, 'w/v' will be added after the percentages of the active substances. Where there is a lack of space, an asterisk will be added next to the percentages with an explanatory note placed close to the Veterinary Medicinal Product name.]

Clear amber spot-on solution.

3. PACKAGE SIZE

0.67 ml

4. TARGET SPECIES

Dogs 2 - 10 kg

5. INDICATIONS

Read the package leaflet for full instructions and for user and environmental precautions.
[More information is provided on the interior side of the combined label package leaflet, see the corresponding package leaflet template.]

6. ROUTES OF ADMINISTRATION

Spot-on
Read the package leaflet for full instructions and for user and environmental precautions
[More information is provided on the interior side of the combined label package leaflet, see the corresponding package leaflet template.]

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C. Store in the original packaging.

Store in a dry place. Flammable.

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 HOLDERS

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 61700/3074

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
{FRONTLINE PLUS SPOT-ON DOG S 1 pipette}

The Immediate packaging is a pipette: the information below appears on the shell or on the opercula of the pipette.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTLINE PLUS
[Pictogram of a drop of veterinary medicinal product falling from a pipette on the skin of the animal thus showing the route of administration]

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

0.67 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS BLISTERS OR STRIPS
{FRONTLINE PLUS SPOT-ON DOG S Box of 1 pipette: 1 blister of 1 pipette; Box of 3 pipettes: 1 blister of 3 pipettes; Box of 4 pipettes: 1 blister of 4 pipettes; Box of 6 pipettes: 2 blisters of 3 pipettes}

The blister package is the same in both cases: the information below appears on the blister shell or on the blister cap of the blister package.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTLINE PLUS

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Fipronil 67 mg / (S) Methoprene 60.30 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET
Box of 1 pipette
Box of 3 pipettes
Box of 4 pipettes
Box of 6 pipettes
The leaflet described below applies to Case N°2 where a package leaflet is added in the packaging.
In case N°1 no leaflet is needed.

1. Name of the veterinary medicinal product

FRONTLINE PLUS DOG S

2. Composition

Each 0.67 ml pipette contains:

Active substances:
Fipronil .....67.00 mg
(S)-methoprene.....60.30 mg

Excipients:
Butylhydroxyanisole (E320) .....0.13 mg
Butylhydroxytoluene (E321).....0.07 mg

Clear amber spot-on solution.

3. Target species

Dogs.

4. Indications for use

For the treatment of dogs weighing 2-to-10 kg bodyweight.

The treatment and prevention of flea and tick infestations and/or biting lice.
- Treatment of flea infestations (*Ctenocephalides* spp.). Insecticidal efficacy against new infestations with adult fleas persists for 8 weeks. Prevention of the multiplication of fleas for 8 weeks after application by killing flea eggs (ovicidal activity) and larvae (larvicidal activity). By killing the larvae, pupae are prevented from developing.
- Treatment of tick infestations (*Ixodes ricinus, Dermacentor variabilis, Dermacentor reticulatus, Rhipicephalus sanguineus*). The veterinary medicinal product has a persistent acaricidal efficacy for up to 4 weeks against ticks.
- Treatment of infestations with biting lice (*Trichodectes canis*).

5. Contraindications

In the absence of available data, the veterinary medicinal product should not be used on puppies less than 8 weeks old and/or weighing less than 2 kg.
Do not use on rabbits, as adverse events and even death could occur. In absence of studies, the use of the veterinary medicinal product is not recommended in non-target species.
Do not use on sick (e.g. systemic diseases, fever) or convalescent animals.
This veterinary medicinal product is specifically developed for dogs. Do not use in cats and ferrets, as this could lead to overdosing.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

6. Special warnings

Special warnings:
Bathing/immersion in water within 2 days after application of the veterinary medicinal product and more frequent bathing than once a week should be avoided, as no study has been performed to investigate how this affects the efficacy of the veterinary medicinal product. Emollient shampoos can be used prior to treatment but reduce the duration of protection against fleas to approximately 5 weeks when used weekly after application of the veterinary medicinal product. Weekly bathing with a 2% chlorhexidine medicated shampoo did not affect efficacy against fleas during a 6 week long study.

There may be an attachment of a few ticks. For this reason, a transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.

In case of infestation, carpets and non-washable furnishings should be treated with an appropriate insecticide household spray to kill eggs and larvae already in the home. Wash all pet bedding at 60°C as fleas often infest the animal's regular resting areas. Vacuum the whole house, including under furniture.

Other pets living in the same household should also be treated with a suitable veterinary medicinal product.

Special precautions for safe use in the target species:
For external use only.
Avoid contact with the animal's eyes.

It is important to make sure that the veterinary medicinal product is applied to an area where the animal cannot lick it off and to make sure that animals do not groom each other following treatment until the application site is dry.

Special precautions to be taken by the person administering the veterinary medicinal product to
animals:
Keep pipettes in original packaging until ready to use. In order to prevent children from getting access to used pipettes, dispose of used pipettes immediately.

This veterinary medicinal product can cause mucous membrane, skin and eye irritation. Therefore, contact of the veterinary medicinal product with mouth, skin and eyes should be avoided.

In the event of accidental exposure to the eye, it should be rinsed carefully with water.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
People with a known hypersensitivity (allergy) to insecticides, such as Fipronil or (S)-methoprene, or to alcohol should avoid contact with this veterinary medicinal product.
Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.

Wash hands after use.

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 are not allowed to sleep with owners, especially children.

Do not smoke, drink or eat during application.

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 alcohol carrier may have adverse effects on painted, varnished or other household surfaces or furnishings.

Pregnancy and lactation:
The veterinary medicinal product can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Do not use simultaneously with other flea products which are applied directly on to the animal.

Overdose:
Do not overdose.
The risk of experiencing adverse effects may increase when overdosing (see section 8 “Adverse Events”), so dogs should always be treated with the correct pipette size according to bodyweight.

No adverse events were observed in target animal safety studies in 8 week-old puppies, growing dogs and dogs weighing about 2 kg treated once at 5 times the recommended dose.

7. Adverse events

Dogs:
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Application site reactions (skin discoloration[1], localised hair loss[1], itching[1], reddening[1]).
Generalised itching or hair loss. Hypersalivation[2], vomiting, respiratory signs.
Increased sensitivity to stimulation[3], depression[3], other nervous signs[3]

[1] Transient.
[2] If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.
[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 the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details on this label, or via your national reporting system:
Website: www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

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

Spot-on

Dogs should be weighed accurately prior to treatment.

One pipette of 0.67 ml (S) per dog weighing over 2 and up to 10 kg, corresponding to a minimum recommended dose of 6.7 mg/kg for fipronil and 6 mg/kg for (S)-methoprene, by topical application to the skin.

In the absence of safety studies, the minimum treatment interval is 4 weeks.

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

9. Advice on correct administration

Method of administration: see outer packaging

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 30°C. Store in the original packaging. Store in a dry place. Flammable.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton 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.

The veterinary medicinal product should not enter water courses as fipronil and (S)-methoprene may be dangerous for fish and other aquatic organisms. Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or empty containers.

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. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription.

14. MARKETING AUTHORISATION NUMBER AND PACK SIZES

Vm 61700/3074

Pack sizes
Blister card of 1 x 0.67 ml pipette
Box of 1 blister card of 1 x 0.67 ml pipette
Box of 1 blister card of 1 x 0.67 ml pipette and two empty blister spaces
Box of 1 blister card of 3 x 0.67 ml pipettes
Box of 1 blister card of 4 x 0.67 ml pipettes
Box of 2 blister cards of 3 x 0.67 ml pipettes

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany
petsUK@boehringer-ingelheim.com
Tel: +353 1 291 3985

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS
4 Chemin du Calquet
31000 Toulouse
France

<Local representatives:>

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

17. Other information

Pharmacodynamics:
Fipronil kills fleas within 24 hours and ticks and lice within 48 hours post-exposure.

AVM-GSL

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet
{FRONTLINE PLUS SPOT-ON DOG S Blister card of 1 pipette}

This packaging is a combined label package-leaflet. The information mentioned below appears on the interior side of this combined label package-leaflet.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTLINE PLUS DOG S

2. COMPOSITION

Each 0.67 ml pipette contains:
Active substances:
Fipronil.....67.00 mg
(S)-methoprene .....60.30 mg
Excipients:
Butylhydroxyanisole (E320).....0.13 mg
Butylhydroxytoluene (E321) .....0.07 mg

FIPRONIL 10% w/v (S) METHOPRENE 9% w/v
[Where there is sufficient space, 'w/v' will be added after the percentages of the active substances. Where there is a lack of space, an asterisk will be added next to the percentages with an explanatory note placed close to the Veterinary Medicinal Product name.]

Clear amber spot-on solution.

3. PACKAGE SIZE

0.67 ml

4. TARGET SPECIES

Dogs

5. INDICATIONS FOR USE

Indications for use

For the treatment of dogs weighing 2-to-10 kg bodyweight.

The treatment and prevention of flea and tick infestations and/or biting lice.
- Treatment of flea infestations (*Ctenocephalides* spp.). Insecticidal efficacy against new infestations with adult fleas persists for 8 weeks. Prevention of the multiplication of fleas for 8 weeks after application by killing flea eggs (ovicidal activity) and larvae (larvicidal activity). By killing the larvae, pupae are prevented from developing.
- Treatment of tick infestations (*Ixodes ricinus, Dermacentor variabilis, Dermacentor reticulatus, Rhipicephalus sanguineus*). The veterinary medicinal product has a persistent acaricidal efficacy for up to 4 weeks against ticks.

- Treatment of infestations with biting lice (*Trichodectes canis*).

6. CONTRAINDICATIONS

Contraindications

In the absence of available data, the veterinary medicinal product should not be used on puppies less than 8 weeks old and/or weighing less than 2 kg.
Do not use on sick (e.g. systemic diseases, fever) or convalescent animals.
Do not use on rabbits, as adverse drug reactions and even death could occur.
In absence of studies, the use of the veterinary medicinal product is not recommended in non-target species.
This veterinary medicinal product is specifically developed for dogs. Do not use in cats and ferrets, as this could lead to overdosing.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

7. SPECIAL WARNINGS

Special warnings

Bathing/immersion in water within 2 days after application of the veterinary medicinal product and more frequent bathing than once a week should be avoided, as no study has been performed to investigate how this affects the efficacy of the veterinary medicinal product. Emollient shampoos can be used prior to treatment but reduce the duration of protection against fleas to approximately 5 weeks when used weekly after application of the veterinary medicinal product. Weekly bathing with a 2% chlorhexidine medicated shampoo did not affect efficacy against fleas during a 6 week long study.

There may be an attachment of a few ticks. For this reason, a transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.

In case of infestation, carpets and non-washable furnishings should be treated with an appropriate insecticide household spray to kill eggs and larvae already in the home. Wash all pet bedding at 60°C as fleas often infest the animal's regular resting areas. Vacuum the whole house, including under furniture.

Other pets living in the same household should also be treated with a suitable veterinary medicinal product.

<u>Special precautions for safe use in the target species:</u>
For external use only.
Avoid contact with the animal's eyes.

It is important to make sure that the veterinary medicinal product is applied to an area where the animal cannot lick it off and to make sure that animals do not groom each other following treatment until the application site is dry.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Keep pipettes in original packaging until ready to use. In order to prevent children from getting access to used pipettes, dispose of used pipettes immediately.
This veterinary medicinal product can cause mucous membrane, skin and eye irritation. Therefore, contact of the veterinary medicinal product with mouth, skin and eyes should be avoided.
In the event of accidental exposure to the eye, it should be rinsed carefully with water.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

People with a known hypersensitivity (allergy) to insecticides, such as Fipronil or (S)-methoprene, or to alcohol should avoid contact with this veterinary medicinal product. Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.

Wash hands after use.

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 are not allowed to sleep with owners, especially children.

Do not smoke, drink or eat during application.

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 alcohol carrier may have adverse effects on painted, varnished or other household surfaces or furnishings.

Pregnancy and lactation:
The veterinary medicinal product can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Do not use simultaneously with other flea products which are applied directly on to the animal.

Overdose:
Do not overdose.
The risk of experiencing adverse effects may increase when overdosing (see section 8 “Adverse Events”), so dogs should always be treated with the correct pipette size according to bodyweight.

No adverse events were observed in target animal safety studies in 8 week-old puppies, growing dogs and dogs weighing about 2 kg treated once at 5 times the recommended dose.

8. ADVERSE EVENTS

Adverse events

Dogs:
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Application site reactions (skin discoloration[1], localised hair loss[1], itching[1], reddening[1]).
Generalised itching or hair loss. Hypersalivation[2], vomiting, respiratory signs.
Increased sensitivity to stimulation[3], depression[3], other nervous signs[3].

[1] Transient.
[2] If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.
[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 the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details on this label, or via your national reporting system:
Website: www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

9. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

Spot-on

Dogs should be weighed accurately prior to treatment.

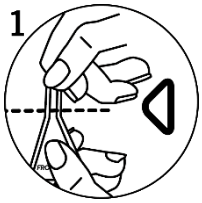
One pipette of 0.67 ml (S) per dog weighing over 2 and up to 10 kg, corresponding to a minimum recommended dose of 6.7 mg/kg for fipronil and 6 mg/kg for (S)-methoprene, by topical application to the skin.
In the absence of safety studies, the minimum treatment interval is 4 weeks.

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

10. ADVICE ON CORRECT ADMINISTRATION

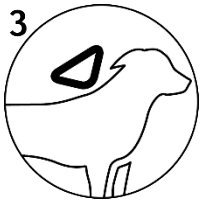
Advice on correct administration

METHOD OF ADMINISTRATION
1- Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette. Snap back the tip.



2 - Part the coat on the back of the animal at the base of the neck in front of the shoulder blades until the skin is visible.

3- Place the tip of the pipette on the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin in one spot.



Temporary changes to the coat (clumped/greasy hair) may be noted at the application site.

11. WITHDRAWAL PERIODS

Withdrawal periods: not applicable.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Do not store above 30°C. Store in the original packaging. Store in a dry place.
Flammable.
Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the blister card after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater.

This veterinary medicinal product should not enter water courses as fipronil and (S)-methoprene may be dangerous for fish and other aquatic organisms. Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or empty containers.

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.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBER AND PACK SIZES

Vm 61700/3074

Pack sizes
Blister card of 1 x 0.67 ml pipette
Box of 1 blister card of 1 x 0.67 ml pipette
Box of 1 blister card of 1 x 0.67 ml pipette and two empty blister spaces
Box of 1 blister card of 3 x 0.67 ml pipettes
Box of 1 blister card of 4 x 0.67 ml pipettes
Box of 2 blister cards of 3 x 0.67 ml pipettes

Not all pack sizes may be marketed.

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany
petsUK@boehringer-ingelheim.com
Tel: +353 1 291 3985

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS
4 chemin du Calquet
31000 Toulouse
France

<Local representatives:>

18. OTHER INFORMATION

Other information

Pharmacodynamics:
Fipronil kills fleas within 24 hours and ticks and lice within 48 hours post-exposure.

AVM-GSL

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

21. BATCH NUMBER

Lot {number}

ADDITIONAL INFORMATION TO APPEAR ON THE OUTER PACKAGE

FRONTLINE PLUS DOG S
Box of 1 pipette (or 3 pipettes or 4 pipettes or 6 pipettes)
Blister card of 1 pipette (only highlighted text)

What does this product do?

For protection against fleas and ticks, and to prevent flea eggs from hatching, apply every 4 weeks*

Kills fleas on your dog for 8 weeks.

Prevents the development of flea eggs, larvae and pupae for 8 weeks.

Kills ticks on your dog for up to 4 weeks.

Kills biting lice.

Suitable for:

Dogs 8 weeks or older.

Pregnant and lactating dogs.

How to treat a home infestation:

In addition to treating your pet follow the 3 steps below:

1) Use a household flea spray on carpets and non-washable furnishings to kill eggs and larvae already in the home.

2) Wash all pet bedding at 60°C

3) Vacuum the whole house, including under furniture.

*Before every use, read the information on the inside of the box/in the package leaflet for full instructions and all warnings.

Approved 28 September 2026
Gavin Hall