

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

FRONTLINE PLUS SPOT-ON DOG XL [UK]

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 XL [UK]

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 Product name.]

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Clear amber solution containing:

Fipronil	402.00 mg
(S)-methoprene	361.80 mg
Butylhydroxyanisole (E320)	0.80 mg
Butylhydroxytoluene (E321)	0.40 mg
Excipient(s): q.s.....	4.02 ml

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

[if in the case of a box of 1 pipette:]

1 PIPETTE OF 4.02 ml

[if in the case of a box of 3 pipettes:]

3 PIPETTES OF 4.02 ml

[if in the case of a box of 4 pipettes:]

4 PIPETTES OF 4.02 ml

[if in the case of a box of 6 pipettes:]

6 PIPETTES OF 4.02 ml

5. TARGET SPECIES

DOG XL over 40 kg

6. INDICATION(S)

For the treatment of dogs weighing over 40 kg bodyweight

- To be used against infestations with fleas, alone or in association with ticks 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 by inhibiting the development of eggs (ovicidal activity), larvae and pupae (larvicidal activity) originating from eggs laid by adult fleas for eight weeks after application.
 - Treatment of tick infestations (*Ixodes ricinus*, *Dermacentor variabilis*, *Dermacentor reticulatus*, *Rhipicephalus sanguineus*). The product has a persistent acaricidal efficacy for up to 4 weeks against ticks (based on experimental data).
 - Treatment of infestations with biting lice (*Trichodectes canis*).
- Fipronil kills fleas within 24 hours and ticks and lice within 48 hours post-exposure.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Spot-on

METHOD OF ADMINISTRATION

1-Take the pipette out of its packaging. 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.



Dosage

One pipette of 4.02 ml (XL) per dog weighing over 40 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.

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

8. WITHDRAWAL PERIOD

[NOT APPLICABLE]

9. SPECIAL WARNING(S), IF NECESSARY

For external use only.

Use during pregnancy and lactation

The product can be used during pregnancy and lactation.

Precautions

It is important to make sure that the product is applied to an area where the animal cannot lick it off and to make sure that animals do not lick each other following treatment.

When treating infestations of parasites, all in-contact animals should be treated with an appropriate product at the same time. Do not use simultaneously with other flea products which are applied directly on to the animal.

Bathing/immersion in water within 2 days after application of the 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 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 product. Weekly bathing with a 2% chlorhexidine medicated shampoo did not affect efficacy against fleas during a 6 week long study. The duration of protection of the product is not affected by immersion in water or weekly shampooing with a 2% Chlorhexidine shampoo for up to 6 weeks when carried out 2 days after treatment.

Avoid contact with the animal's eyes.

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.

Fleas from pets often infest the animal's basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated, in case of massive infestation and at the beginning of the control measures, with a suitable insecticide and vacuumed regularly.

Animals should be weighed accurately prior to treatment.

Contraindications

In the absence of available data, the product should not be used on puppies less than 8 weeks old.

Do not use on sick (e.g. systemic diseases, fever) or convalescent animals.

Do not use in rabbits, as adverse drug reactions and even mortality could occur. In absence of studies, the use of the product is not recommended in non-target species.

This 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.

Undesirable Effects

Among the very rare suspected adverse reactions, transient skin reactions on the application site (skin discoloration, local hair loss, itching, redness) and general itching or hair loss have been reported after use. Excessive salivation, reversible nervous signs (increased sensitivity to stimulation, depression, other nervous signs), vomiting or respiratory symptoms have also been observed after use.

If licking occurs, a brief period of excessive salivation may be observed due mainly to the nature of the carrier.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

Do not overdose.

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

Overdose

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

The risk of experiencing adverse effect may however increase with overdosing (see Undesirable Effect) so animals should always be treated with the correct pipette size according to bodyweight.

User warnings

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

If the product is accidentally swallowed, seek medical advice immediately and show the package leaflet to the physician.

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

After accidental exposure the eye should be rinsed carefully with pure 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.

Other Precautions

Fipronil and (S) methoprene may adversely affect aquatic organisms. Dogs should not be allowed to swim in watercourses for 2 days after application.

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

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

Do not use this veterinary medicinal product after the expiry date stated on the package after EXP.

The expiry date refers to the last day of the month.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Fipronil and (S)-methoprene may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers

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

For animal treatment only.

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

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK
petsUK@boehringer-ingelheim.com

16. MARKETING AUTHORISATION NUMBER(S)

AVM-GSL Vm 08327/4271

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

Additional information:

[Manufacturer]
Boehringer Ingelheim Animal Health France SCS
4 chemin du Calquet
31000 Toulouse, France

18. FURTHER INFORMATION

Blister card of 1 x 4.02 ml pipette
Box of 1 blister card of 1 x 4.02 ml pipette and two empty blister spaces
Box of 1 blister card of 3 x 4.02 ml pipettes
Box of 1 blister card of 4 x 4.02 ml pipettes
Box of 2 blister cards of 3 x 4.02 ml pipettes
Not all pack sizes may be marketed.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

FRONTLINE PLUS SPOT-ON DOG XL [UK]

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 cannot 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 XL [UK]

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 Product name.]

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition

Fipronil	402.00 mg
(S)-methoprene	361.80 mg
Butylhydroxyanisole (E320)	0.80 mg
Butylhydroxytoluene (E321)	0.40 mg
Excipient(s): q.s.	4.02 ml

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

[if in the case of a box of 1 pipette:]

1 PIPETTE OF 4.02 ml

[if in the case of a box of 3 pipettes:]

3 PIPETTES OF 4.02 ml

[if in the case of a box of 4 pipettes:]

4 PIPETTES OF 4.02 ml

[if in the case of a box of 6 pipettes:]

6 PIPETTES OF 4.02 ml

5. TARGET SPECIES

DOG XL over 40 kg

6. INDICATION(S)

Read the package leaflet before use.

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Spot-on

METHOD OF ADMINISTRATION

1-Take the pipette out of its packaging. 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.



8. WITHDRAWAL PERIOD

[NOT APPLICABLE]

9. SPECIAL WARNING(S), IF NECESSARY

For external use only.
Read the package leaflet before use.

User warnings

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

If the product is accidentally swallowed, seek medical advice immediately and show the package leaflet to the physician.

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

After accidental exposure the eye should be rinsed carefully with pure 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.

[More information is provided in packaging leaflet. See the corresponding template.]

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. 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.

[More information is provided in packaging leaflet. See the corresponding template.]

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

For animal treatment only.

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

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK
petsUK@boehringer-ingelheim.com

16. MARKETING AUTHORISATION NUMBER(S)

AVM-GSL Vm 08327/4271

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

18. FURTHER INFORMATION

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

FRONTLINE PLUS SPOT-ON DOG XL [UK]

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 XL [UK]

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 Product name.]

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

FIPRONIL (S)-METHOPRENE

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

1 PIPETTE OF 4.02 ml

5. TARGET SPECIES

DOG XL over 40 kg

6. INDICATION(S)

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. METHOD AND ROUTE(S) 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.]

8. WITHDRAWAL PERIOD

[Not Applicable]

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet for full instructions and for user and environmental precautions

10. EXPIRY DATE

EXP {MM-YYYY}

11. SPECIAL STORAGE CONDITIONS

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

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

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.]

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

For animal treatment only.

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

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK
petsUK@boehringer-ingelheim.com

16. MARKETING AUTHORISATION NUMBER(S)

AVM-GSL Vm 08327/4271

17. MANUFACTURER'S BATCH NUMBER

BN{Number}

18. FURTHER INFORMATION

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

FRONTLINE PLUS SPOT-ON DOG XL [UK]

1 pipette

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTLINE PLUS [UK]

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

FIPRONIL 402 mg (S)-METHOPRENE 361.80 mg

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

4.02 ml

4. ROUTE(S) OF ADMINISTRATION

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

5. WITHDRAWAL PERIOD

[Not Applicable]

6. BATCH NUMBER

{number}

7. EXPIRY DATE

{MM-YYYY}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

[Pictogram of a dog indicating the veterinary use]

[In Addition]
BOEHRINGER

[Pictogram of a dog indicating the target species]

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

FRONTLINE PLUS SPOT-ON DOG XL [UK]

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. NAME OF THE MARKETING AUTHORISATION HOLDER

BOEHRINGER

3. EXPIRY DATE

{MM-YYYY}

4. BATCH NUMBER

{number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

[or]

AD US. VET. - USAGE VETERINAIRE - FOR VETERINARY USE

6. ADDITIONAL INFORMATION

4.02 ml

FIPRONIL 10 % w/v METHOPRENE 9 % w/v

B. PACKAGE LEAFLET

**PACKAGE LEAFLET FOR:
FRONTLINE PLUS SPOT-ON DOG XL [UK]**

**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 added.*

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

Marketing authorisation holder:

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Manufacturer responsible for batch release:

Boehringer Ingelheim Animal Health France SCS
4 chemin du Calquet
31000 Toulouse
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTLINE PLUS SPOT-ON DOG XL [UK]

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 Product name.]

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER
INGREDIENT(S)**

Clear amber solution containing:

- Fipronil 402.00 mg
- (S)-methoprene 361.80 mg
- Butylhydroxyanisole (E320) 0.80 mg
- Butylhydroxytoluene (E321) 0.40 mg

Excipient(s): q.s 4.02 ml

4. INDICATION(S)

For the treatment of dogs weighing over 40 kg bodyweight

- To be used against infestations with fleas, alone or in association with ticks 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 by inhibiting the development of eggs (ovicidal activity),

larvae and pupae (larvicidal activity) originating from eggs laid by adult fleas for eight weeks after application.

- Treatment of tick infestations (*Ixodes ricinus*, *Dermacentor variabilis*, *Dermacentor reticulatus*, *Rhipicephalus sanguineus*). The product has a persistent acaricidal efficacy for up to 4 weeks against ticks (based on experimental data).
- Treatment of infestations with biting lice (*Trichodectes canis*).

5. CONTRAINDICATIONS

In the absence of available data, the product should not be used on puppies less than 8 weeks old.

Do not use on sick (e.g. systemic diseases, fever) or convalescent animals.

Do not use in rabbits, as adverse drug reactions and even mortality could occur. In absence of studies, the use of the product is not recommended in non-target species.

This 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. ADVERSE REACTIONS

Among the very rare suspected adverse reactions, transient skin reactions on the application site (skin discoloration, local hair loss, itching, redness) and general itching or hair loss have been reported after use. Excessive salivation, reversible nervous signs (increased sensitivity to stimulation, depression, other nervous signs), vomiting or respiratory symptoms have also been observed after use.

If licking occurs, a brief period of excessive salivation may be observed due mainly to the nature of the carrier.

Do not overdose.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, 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

Target species: Dogs.

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

Route of administration: external, by topical application to the skin.

Dosage for a dog over 40 kg of weight: One pipette of 4.02 ml per dog. In the absence of safety studies, the minimum treatment interval is 4 weeks.

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

9. ADVICE ON CORRECT ADMINISTRATION

Method of administration: see outer packaging

10. WITHDRAWAL PERIOD

[Not Applicable]

11. SPECIAL STORAGE PRECAUTIONS

Storage

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

Keep out of the sight and reach of children.

Do not use this veterinary medicinal product after the expiry date stated on the carton after EXP.

The expiry date refers to the last day of the month.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

It is important to make sure that the product is applied to an area where the animal cannot lick it off and to make sure that animals do not lick each other following treatment.

When treating infestations of parasites, all in-contact animals should be treated with an appropriate product at the same time. Do not use simultaneously with other flea products which are applied directly on to the animal.

Bathing/immersion in water within 2 days after application of the 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 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 product. Weekly bathing with a 2% chlorhexidine medicated shampoo did not affect efficacy against fleas during a 6 week long study. The duration of protection of the product is not affected by immersion in water or weekly shampooing with a 2% Chlorhexidine shampoo for up to 6 weeks when carried out 2 days after treatment.

Avoid the contact with the animal's eyes.

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.

Fleas from pets often infest the animal's basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated, in case of massive infestation and at the beginning of the control measures, with a suitable insecticide and vacuumed regularly.

Animals should be weighed accurately prior to treatment.

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

If the product is accidentally swallowed, seek medical advice immediately and show the package leaflet to the physician.

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

After accidental exposure the eye should be rinsed carefully with pure 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.

Other Precautions

Fipronil and (S) methoprene may adversely affect aquatic organisms. Dogs should not be allowed to swim in watercourses for 2 days after application.

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

Overdose (symptoms, emergency procedures, antidotes):

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

The risk of experiencing adverse effect may however increase with overdosing (see Undesirable Effects) so animals should always be treated with the correct pipette size according to bodyweight.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Fipronil and (S)-methoprene may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2021

15. OTHER INFORMATION

Use during pregnancy, lactation or lay

The product can be used during pregnancy and lactation.

Pharmacodynamic properties

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

Blister card of 1 x 4.02 ml pipette

Box of 1 blister card of 1 x 4.02 ml pipette and two empty blister spaces

Box of 1 blister card of 3 x 4.02 ml pipettes

Box of 1 blister card of 4 x 4.02 ml pipettes
Box of 2 blister cards of 3 x 4.02 ml pipettes

Not all pack sizes may be marketed.

AVM-GSL Vm 08327/4271

FRONTLINE PLUS SPOT ON DOG XL [UK]

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

Marketing authorisation holder

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Manufacturer responsible for batch release:

Boehringer Ingelheim Animal Health France SCS
4 chemin du Calquet
31000 Toulouse
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTLINE PLUS DOG XL [UK]

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 Product name.]

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Clear amber solution containing:

- Fipronil 402.00 mg
- (S)-methoprene 361.80 mg
- Butylhydroxyanisole (E320) 0.80 mg
- Butylhydroxytoluene (E321) 0.40 mg

Excipient(s): q.s 4.02 ml

4. INDICATION(S)

For the treatment of dogs weighing over 40 kg bodyweight

- To be used against infestations with fleas, alone or in association with ticks 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 by inhibiting the development of eggs (ovicidal activity), larvae and pupae (larvicidal activity) originating from eggs laid by adult fleas for eight weeks after application.
- Treatment of tick infestations (*Ixodes ricinus*, *Dermacentor variabilis*, *Dermacentor reticulatus*, *Rhipicephalus sanguineus*). The product has a persistent acaricidal efficacy for up to 4 weeks against ticks (based on experimental data).
- Treatment of infestations with biting lice (*Trichodectes canis*).

5. CONTRAINDICATIONS

In the absence of available data, the product should not be used on puppies less than 8 weeks old.

Do not use on sick (e.g. systemic diseases, fever) or convalescent animals.

Do not use in rabbits, as adverse drug reactions and even mortality could occur. In absence of studies, the use of the product is not recommended in non-target species.

This 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. ADVERSE REACTIONS

Among the very rare suspected adverse reactions, transient skin reactions on the application site (skin discoloration, local hair loss, itching, redness) and general itching or hair loss have been reported after use. Excessive salivation, reversible nervous signs (increased sensitivity to stimulation, depression, other nervous signs), vomiting or respiratory symptoms have also been observed after use.

If licking occurs, a brief period of excessive salivation may be observed due mainly to the nature of the carrier.

Do not overdose.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, 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(S) AND METHOD OF ADMINISTRATION

Route of administration: external, by topical application to the skin

Dosage for a dog from over 40 kg of weight: One pipette of 4.02 ml per dog corresponding to a minimum recommended dose of 6.7 mg/kg for fipronil and 6 mg/kg for (S)-methoprene. In the absence of safety studies, the minimum treatment interval is 4 weeks.

9. ADVICE ON CORRECT ADMINISTRATION

Method of administration

1-Take the pipette out of its packaging.

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.



10. WITHDRAWAL PERIOD

[Not Applicable]

11. SPECIAL STORAGE PRECAUTIONS

Storage

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

Keep out of the sight and reach of children.

Do not use this veterinary medicinal product after the expiry date stated on the package after EXP.

The expiry date refers to the last day of the month.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

It is important to make sure that the product is applied to an area where the animal cannot lick it off and to make sure that animals do not lick each other following treatment.

When treating infestations of parasites, all in-contact animals should be treated with an appropriate product at the same time. Do not use simultaneously with other flea products which are applied directly on to the animal.

Bathing/immersion in water within 2 days after application of the 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 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 product. Weekly bathing with a 2% chlorhexidine medicated shampoo did not affect efficacy against fleas during a 6 week long study. The duration of protection of the product is not affected by immersion in water or weekly shampooing with a 2% Chlorhexidine shampoo for up to 6 weeks when carried out 2 days after treatment.

Avoid the contact with the animal's eyes.

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.

Fleas from pets often infest the animal's basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated, in case of massive

infestation and at the beginning of the control measures, with a suitable insecticide and vacuumed regularly.
Animals should be weighed accurately prior to treatment.

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

If the product is accidentally swallowed, seek medical advice immediately and show the package leaflet to the physician.

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

After accidental exposure the eye should be rinsed carefully with pure 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.

Other Precautions

Fipronil and (S) methoprene may adversely affect aquatic organisms. Dogs should not be allowed to swim in watercourses for 2 days after application.

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

Overdose (symptoms, emergency procedures, antidotes):

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

The risk of experiencing adverse effect may however increase with overdosing (see Undesirable Effects) so animals should always be treated with the correct pipette size according to bodyweight.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Fipronil and (S)-methoprene may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2021

15. OTHER INFORMATION

Use during pregnancy, lactation or lay

The product can be used during pregnancy and lactation.

Pharmacodynamic properties

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

Blister card of 1 x 4.02 ml pipette

Box of 1 blister card of 1 x 4.02 ml pipette and two empty blister spaces

Box of 1 blister card of 3 x 4.02 ml pipettes

Box of 1 blister card of 4 x 4.02 ml pipettes

Box of 2 blister cards of 3 x 4.02 ml pipettes

Not all pack sizes may be marketed.

AVM-GSL Vm 08327/4271

ADDITIONAL INFORMATION TO APPEAR ON THE OUTER PACKAGE

FRONTLINE PLUS SPOT ON DOG XL over 40 kg [UK]
Box of 1 pipette (or 3 pipettes or 4 pipettes or 6 pipettes)
Blister card of 1 pipette (only highlighted text)

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

What does this product do?

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.

{icons}

How to treat a home infestation

In addition to treating your pet follow the 2 steps below:

- 1) Use a household flea treatment to kill eggs and larvae already in the home.
- 2) Regularly vacuum your carpets and furnishings.

For dogs 8 weeks or older. Can be used during pregnancy and lactation.

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

Approved: 08/03/21

