

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

FRONTLINE COMBO SPOT ON DOG XL

Box of 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 COMBO SPOT-ON DOG XL

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 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*).

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

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

2-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.

3-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. 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 (S) 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

Frontline Combo Spot On Dog 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.

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.

Avoid contact with the animal's eyes.

Dogs should not be allowed to swim in watercourses for 2 days after application (See section Disposal of waste materials)

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

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.

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 with 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.

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.

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

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

Animals or operators with a known hypersensitivity to insecticides or alcohol should avoid contact with Frontline Combo Spot On Dog. 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.

10. EXPIRY DATE

EXP {MM-YYYY}

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Store in the original package.
Do not use after the expiry date stated on the package after EXP.

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

Fipronil and (S)-methoprene may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers. Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

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 REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

IE: Boehringer Ingelheim Vetmedica GmbH, Ingelheim, Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/5016

VPA 10454/047/004

17. MANUFACTURER'S BATCH NUMBER

BN {number}

Additional information:

[Manufacturer]

Boehringer Ingelheim Animal Health France SCS4 chemin du Calquet
31300 Toulouse, France

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

FRONTLINE COMBO SPOT ON DOG XL

Box of 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 COMBO SPOT-ON DOG XL

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.....	4.02ml

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

[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
- 2-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.
- 3-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. 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.
[More information is provided in the package leaflet. See the corresponding template.]

10. EXPIRY DATE

EXP. {MM-YYYY}

11. SPECIAL STORAGE CONDITIONS

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

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 the package 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 REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

IE: Boehringer Ingelheim Vetmedica GmbH, Ingelheim, Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/5016

VPA 10454/047/004

17. MANUFACTURER’S BATCH NUMBER

BN {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

FRONTLINE COMBO SPOT ON DOG XL

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 COMBO SPOT-ON DOG XL
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 before use.
[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 before use.
[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

For Dogs from 8 weeks of age.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {MM-YYYY}

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.
[More information is provided on the interior side of the combined label package leaflet, see the corresponding package leaflet template.]

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

Read the package leaflet before use.
[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 REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

IE: Boehringer Ingelheim Vetmedica GmbH, Ingelheim, Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/5016

VPA 10454/047/004

17. MANUFACTURER’S BATCH NUMBER

BN {Number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

FRONTLINE COMBO SPOT ON DOG XL

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 COMBO

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

FIPRONIL 402 mg (S)-METHOPRENE 361.8 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]

Name of the MAH to be completed nationally

[Pictogram of a dog indicating the target species]

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

FRONTLINE COMBO SPOT ON DOG XL

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 COMBO SPOT-ON DOG XL
FIPRONIL (S) METHOPRENE

2. NAME OF THE MARKETING AUTHORISATION HOLDER

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

IE: Boehringer Ingelheim Vetmedica GmbH, Ingelheim, Germany

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

FRONTLINE COMBO SPOT-ON DOG XL

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:

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

IE: Boehringer Ingelheim Vetmedica GmbH, Ingelheim, Germany

Manufacturer responsible for batch release:

Boehringer Ingelheim Animal Health France SCS
4 chemin du Calquet
31300 Toulouse
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTLINE COMBO SPOT-ON DOG XL

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)

Frontline Combo Spot On Dog is a 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*).

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

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 with 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.

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 hairloss 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.

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 reach and sight of children.

Do not use after the expiry date stated on the carton after EXP.

12. SPECIAL WARNING(S)

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.

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.

Dogs should not be allowed to swim in watercourses for 2 days after application (see section disposal of waste materials)

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.

Overdose

No undesirable effects were observed in target animal safety studies in 8 week-old puppies, growing dogs and dogs weighing about 2 kg treated once a month 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.

User warnings

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

Animals or operators with a known hypersensitivity to insecticides or alcohol should avoid contact with Frontline Combo Spot On Dog. 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.

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

Fipronil and (S)-methoprene may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers. Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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 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.

FRONTLINE COMBO SPOT-ON DOG XL
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:

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

IE: Boehringer Ingelheim Vetmedica GmbH, Ingelheim, Germany

Manufacturer responsible for batch release:

Boehringer Ingelheim Animal Health France SCS
4 chemin du Calquet
31300 Toulouse
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTLINE COMBO SPOT-ON DOG XL

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)

Frontline Combo Spot On Dog is a 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*).

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

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 with 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.

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.

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 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

Tack 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. 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. 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 reach and sight of children.

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

12. SPECIAL WARNING(S)

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.

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.

Dogs should not be allowed to swim in watercourses for 2 days after application (see section disposal of waste materials)

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.

Overdose

No undesirable effects were observed in target animal safety studies in 8 week-old puppies, growing dogs and dogs weighing about 2 kg treated once a month 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.

User warnings

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

Animals or operators with a known hypersensitivity to insecticides or alcohol should avoid contact with Frontline Combo Spot On Dog. 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.

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

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

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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 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.

ADDITIONAL INFORMATION TO APPEAR ON THE OUTER PACKAGE

FRONTLINE COMBO SPOT ON DOG XL Over 40 kg

Box of 3 pipettes (or 4 pipettes or 6 pipettes)

Box of 1 pipette (only highlighted text)

Kills fleas on your dog and protects against re-infestation for 8 weeks.

Inhibits the development of flea eggs, flea larvae and pupae for 8 weeks, thus preventing contamination of your dog's environment for the same period.

Kills ticks on your dog and protects against re-infestation for up to 4 weeks.

Kills biting lice.

The duration of protection of FRONTLINE COMBO Spot-On 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.

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

Prevents contamination of the environment of treated animals with the immature stages of fleas.

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Approved 28 May 2020

