PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet {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 402.00 mg / 361.80 mg spot-on solution for dog XL

2. COMPOSITION

Each 4.02 ml pipette contains:

Active substances:
Fipronil.....402.00 mg
(S)-methoprene .....361.80 mg
Excipients:
Butylhydroxyanisole (E320).....0.80 mg
Butylhydroxytoluene (E321) .....0.40 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 Product name.]

Clear amber spot-on solution.

3. PACKAGE SIZE

3 x 4.02 ml
4 x 4.02 ml
6 x 4.02 ml

4. TARGET SPECIES

DOG XL >40 kg

5. INDICATIONS FOR USE

Indications for use

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.

6. CONTRAINDICATIONS

Contraindications

In the absence of available data, the product should not be used on puppies less than 8 weeks old.
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.
Do not use on sick (e.g. systemic diseases, fever) or convalescent animals.
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.

7. SPECIAL WARNINGS

Special warnings

For external use only.
Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of based on its epidemiological features, for each individual 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.
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.

Other animals living in the same household should also be treated with a suitable product.

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

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This product can cause mucous membrane, skin and eye irritation. Therefore, contact of the product with mouth, skin and eyes should be avoided.
People with a known hypersensitivity to fipronil or (S)-methoprene, or alcohol should avoid contact with the veterinary medicinal 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.

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).

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

Overdose:
Do not overdose.
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 five times the recommended dose.
The risk of experiencing adverse events may however increase with overdosing (see Adverse Events) so animals should always be treated with the correct pipette size according to bodyweight.

8. ADVERSE EVENTS

Adverse events

Dogs:
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Application site reactions (skin discoloration[1], 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: https://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 use.

The minimum dose is 6.7 mg/kg bw of fipronil and 6 mg/kg bw of (S)-methoprene, corresponding to one pipette of 4.02 ml (XL) per dog (weighing over 40 kg).
To ensure a correct dosage, body weight should be determined as accurately as possible. Underdosing could result in ineffective use and may favour resistance development.
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.

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

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct 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.

11. WITHDRAWAL PERIODS

Withdrawal periods: not applicable.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

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 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.

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 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 NUMBERS AND PACK SIZES

Vm 61700/5019

Pack sizes
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.

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

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

Local representatives and contact details to report suspected adverse reactions:
United Kingdom (Great Britain)
Boehringer Ingelheim Animal Health UK Limited
Bracknell, RG12 8YS, UK
Tel: + 44 1344 746957

United Kingdom (Northern Ireland)
Boehringer Ingelheim Vetmedica GmbH
D-55216 Ingelheim/Rhein, Germany
Tel: +353 1 291 3985

18. OTHER INFORMATION

Other information

POM-V	Veterinary medicinal product subject to prescription

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 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

2. STATEMENT OF ACTIVE SUBSTANCES

Each 4.02 ml pipette contains:
Fipronil.....402.00 mg
(S)-methoprene .....361.80 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 Product name.]

3. PACKAGE SIZE

3 x 4.02 ml
4 x 4.02 ml
6 x 4.02 ml

4. TARGET SPECIES

DOG XL >40 kg

5. INDICATIONS

For products not subject to veterinary prescription:
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.

6. ROUTES OF ADMINISTRATION

Spot-on use

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.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 61700/5019

15. BATCH NUMBER

Lot {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

2. STATEMENT OF ACTIVE SUBSTANCES

Each 4.02 ml pipette contains:
Fipronil.....402.00 mg
(S)-methoprene .....361.80 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 Product name.]

3. PACKAGE SIZE

4.02 ml

4. TARGET SPECIES

DOG XL >40 kg

5. INDICATIONS

For Dogs from 8 weeks of age.
For products not subject to veterinary prescription:
Kills fleas
Kills ticks
Kills biting lice
Prevents contamination of the environment of treated animals with the immature stages of fleas.

6. ROUTES OF ADMINISTRATION

Spot-on use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 61700/5019

15. BATCH NUMBER

Lot {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 opercula of the pipette.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTLINE COMBO

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

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

4.02 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 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 DOG XL

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Fipronil 402.0 mg / (S) Methoprene 361.8 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET
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 of the veterinary medicinal product

Frontline Combo 402.00 mg / 361.80 mg Spot-on Solution for Dog XL

2. Composition

Each 4.02 ml pipette contains:

Active substances:
Fipronil .....402.00 mg
(S)-methoprene .....361.80 mg

Excipients:
Butylhydroxyanisole (E320) .....0.80 mg
Butylhydroxytoluene (E321) .....0.40 mg

Clear amber spot-on solution.

3. Target species

Dogs (weighing over 40 kg bw).

4. Indications for use

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

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy.
The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of based on its epidemiological features, for each individual 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.

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.

<u>Special precautions for safe use in the target species:</u>

Avoid the contact with the animal’s eyes.
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.

<u>Special precautions to be taken by the person administering the veterinary medicinal product to animals:</u>

This product can cause mucous membrane, skin and eye irritation. Therefore, contact of the product with mouth, skin and eyes should be avoided.
People with a known hypersensitivity to fipronil or (S)-methoprene, or alcohol should avoid contact with the veterinary medicinal 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.

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).

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Overdose:

Do not overdose.
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 five times the recommended dose.
The risk of experiencing adverse event may however increase with overdosing (see Adverse Events) so animals should always be treated with the correct pipette size according to bodyweight.

7. Adverse events

Dogs:
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Application site reactions (skin discoloration[1], 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 at the end of this leaflet, or via your national reporting system:
Website: https://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 use.

The minimum dose is 6.7 mg/kg bw of fipronil and 6 mg/kg bw of (S)-methoprene, corresponding to one pipette of 4.02 ml (XL) per dog (weighing over 40 kg).
To ensure a correct dosage, body weight should be determined as accurately as possible. Underdosing could result in ineffective use and may favour resistance development.

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. 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 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 package.
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.

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 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 61700/5019

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.

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

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

Local representatives and contact details to report suspected adverse reactions:
United Kingdom (Great Britain)
Boehringer Ingelheim Animal Health UK Limited
Bracknell, RG12 8YS, UK
Tel: + 44 1344 746957

United Kingdom (Northern Ireland)
Boehringer Ingelheim Vetmedica GmbH
D-55216 Ingelheim/Rhein, Germany
Tel: +353 1 291 3985

17. Other information

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

POM-V	Veterinary medicinal product subject to prescription

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

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frontline Combo 402.00 mg / 361.80 mg spot-on solution for dog XL

2. COMPOSITION

Each 4.02 ml pipette contains:
Active substances:
Fipronil.....402.00 mg
(S)-methoprene .....361.80 mg
Excipients:
Butylhydroxyanisole (E320).....0.80 mg
Butylhydroxytoluene (E321) .....0.40 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 Product name.]

Clear amber spot-on solution.

3. PACKAGE SIZE

4.02 ml

4. TARGET SPECIES

DOG XL >40 kg

5. INDICATIONS FOR USE

Indications for use

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).

6. CONTRAINDICATIONS

Contraindications

In the absence of available data, the product should not be used on puppies less than 8 weeks old.
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.
Do not use on sick (e.g. systemic diseases, fever) or convalescent animals.
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.

7. SPECIAL WARNINGS

Special warnings

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of based on its epidemiological features, for each individual 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.
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.
Other animals living in the same household should also be treated with a suitable product.

<u>Special precautions for safe use in the target species:</u>

Avoid the contact with the animal's eyes.
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.

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

This product can cause mucous membrane, skin and eye irritation. Therefore, contact of the product with mouth, skin and eyes should be avoided.
People with a known hypersensitivity to fipronil or (S)-methoprene, or alcohol should avoid contact with the veterinary medicinal 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.

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).

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Overdose:

Do not overdose.

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 five times the recommended dose.
The risk of experiencing adverse event may however increase with overdosing (see Adverse Events) so animals should always be treated with the correct pipette size according to bodyweight.

8. ADVERSE EVENTS

Adverse events
Dogs:
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Application site reactions (skin discoloration[1], 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 on this label, 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: https://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 use.

The minimum dose is 6.7 mg/kg bw of fipronil and 6 mg/kg bw of (S)-methoprene, corresponding to one pipette of 4.02 ml (XL) per dog (weighing over 40 kg).
To ensure a correct dosage, body weight should be determined as accurately as possible. Underdosing could result in ineffective use and may favour resistance development.

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

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct 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.
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 package.
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 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 NUMBERS AND PACK SIZES

Vm 61700/5019

Pack sizes
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.

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

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

Local representatives and contact details to report suspected adverse reactions:
United Kingdom (Great Britain)
Boehringer Ingelheim Animal Health UK Limited
Bracknell, RG12 8YS, UK
Tel: + 44 1344 746957

United Kingdom (Northern Ireland)
Boehringer Ingelheim Vetmedica GmbH
D-55216 Ingelheim/Rhein, Germany
Tel: +353 1 291 3985

18. OTHER INFORMATION

Other information

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

POM-V	Veterinary medicinal product subject to prescription

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

21. BATCH NUMBER

Lot {number}

Gavin Hall
Approved: 01 December 2025