

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET (v 9.0) FRONTLINE COMBO SPOT ON CAT {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 50.00 mg / 60.00 mg spot-on solution for cat

**2. COMPOSITION**

Each 0.5 ml pipette contains:

**Active substances:**

Fipronil.....	50.00 mg
(S)-methoprene .....	60.00 mg

**Excipients:**

Butylhydroxyanisole (E320).....	0.10 mg
Butylhydroxytoluene (E321) .....	0.05 mg

FIPRONIL 10% w/v (S) METHOPRENE 12% 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 0.5 ml  
4 x 0.5 ml  
6 x 0.5 ml

**4. TARGET SPECIES**

Cats  
Ferrets

**5. INDICATIONS FOR USE**

**Indications for use**

In cats:

To be used against infestations with fleas, alone or in association with ticks and/or biting lice.

- Elimination of fleas (*Ctenocephalides* spp.). Insecticidal efficacy against new infestations with adult fleas persists for 4 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 six weeks after application.
- Elimination of ticks (*Ixodes ricinus*, *Dermacentor variabilis*, *Rhipicephalus sanguineus*). The product has a persistent acaricidal efficacy for up to 2 weeks against ticks (based on experimental data).
- Elimination of biting lice (*Felicola subrostratus*).

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

In ferrets:

To be used against infestations with fleas, alone or in association with ticks.

- Elimination of fleas (*Ctenocephalides* spp.). Insecticidal efficacy against new infestations with adult fleas persists for 4 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.
- Elimination of ticks (*Ixodes ricinus*). The product has a persistent acaricidal efficacy for 4 weeks against ticks (based on experimental data).

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 kittens less than 8 weeks old and/or weighing less than 1 kg. The product should not be used in ferrets less than 6 months 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.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

## 7. SPECIAL WARNING(S)

### 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.

No data on the effect of bathing/shampooing on the efficacy of the product in cats and ferrets are available. However, based on information available for dogs shampooed as from 2 days after application of the product, it is not recommended to bath animals within 2 days after application of the product.

There may be an attachment of single 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.

Special precautions for safe use in the target species:

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.

The potential toxicity of the product for kittens of less than 8 weeks of age in contact with a treated queen is not documented. Special care should be taken in this case.

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 plain 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:

See section "Special precautions for disposal".

Pregnancy and lactation:

The veterinary medicinal product can be used during pregnancy in cats. For treatment during the lactating period, see above.

Use only according to benefit/risk assessment by a responsible veterinarian in ferrets.

Overdose:

Do not overdose.

The risk of experiencing adverse events may however increase when overdosing (see Adverse Events).

**Cats:**

No adverse events were observed in target animal safety studies in cats and kittens aged 8 weeks and older and weighing about 1 kg treated once a month at five times the recommended dose for six consecutive months.

Itching may occur following treatment.

Overdose application of the product will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will disappear within 24 hours post application.

**Ferrets:**

In ferrets aged 6 months and older and treated once every 2 weeks for four treatments, at five times the recommended dose, body weight loss was observed in some animals.

## **8. ADVERSE EVENTS**

### **Adverse events**

Cats and Ferrets:

**Very rare (<1 animal / 10,000 animals treated, including isolated reports):**

Application site reactions (skin scaling<sup>1</sup>, hair loss<sup>1</sup>, itching<sup>1</sup>, reddening<sup>1</sup>). Generalised itching or hair loss. Hypersalivation<sup>2</sup>, vomiting. Increased sensitivity to stimulation<sup>3</sup>, depression<sup>3</sup>, other nervous signs<sup>3</sup>.

<sup>1</sup> Transient

<sup>2</sup> If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.

<sup>3</sup> 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](mailto: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.

Underdosing could result in ineffective use and may favour resistance development.

Cats:

The minimum dose is 5 mg/kg bw of fipronil and 6 mg/kg bw of (S)-methoprene, corresponding to one pipette of 0.5 ml per cat.

Ferrets:

The dose is 50 mg of fipronil and 60 mg of (S)-methoprene per ferret, corresponding to one pipette of 0.5 ml per ferret.

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

## **10. ADVICE ON CORRECT ADMINISTRATION**

### **Advice on correct administration**

- 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 PERIOD(S)**

**Withdrawal periods:** Not applicable

## **12. SPECIAL STORAGE PRECAUTIONS**

### **Special storage precautions**

Do not store above 25°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.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. 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 08327/5017

### **Pack sizes**

Blister card of 1 x 0.5 ml pipette

Box of 1 blister card of 3 x 0.5 ml pipettes

Box of 1 blister card of 4 x 0.5 ml pipettes

Box of 2 blister cards of 3 x 0.5 ml pipettes

Not all pack sizes may be marketed.

## **16. DATE ON WHICH THE LABEL WAS LAST REVISED**

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](http://www.gov.uk).

## **17. CONTACT DETAILS**

### **Contact details**

#### Marketing authorisation holder:

Boehringer Ingelheim Animal Health UK Ltd  
Ellesfield Avenue  
Bracknell  
Berkshire  
RG12 8YS  
United Kingdom

#### 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 Ltd  
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**

**19. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**20. EXPIRY DATE**

Exp {mm/yyyy}

**21. BATCH NUMBER**

Lot {number}

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

Keep out of the sight and reach of children.

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE FRONTLINE COMBO  
SPOT ON CAT {Box of 3 pipettes (or 4 pipettes or 6 pipettes)}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

FRONTLINE COMBO SPOT-ON CAT

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each 0.5 ml pipette contains:

**Active substances:**

Fipronil.....50.00 mg  
(S)-methoprene .....60.00 mg

**Excipients:**

Butylhydroxyanisole (E320).....0.10 mg  
Butylhydroxytoluene (E321) .....0.05 mg

FIPRONIL 10% w/v (S) METHOPRENE 12% 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 0.5 ml

4 x 0.5 ml

6 x 0.5 ml

**4. TARGET SPECIES**

Cats

Ferrets

**5. INDICATION(S)**

**For products not subject to veterinary prescription:**

Eliminates fleas on your cat and protects against re-infestation for 4 weeks.

Inhibits the development of flea eggs, flea larvae and pupae (for 6 weeks in cats), thus preventing contamination of your pet's environment for the same period.

Eliminates ticks on your cat and protects against re-infestation for up to 2 weeks.

Eliminates biting lice on your cat.

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

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



Eliminates fleas on your ferret and protects against re-infestation for 4 weeks.

Eliminates ticks on your ferret and protects against re-infestation for up to 4 weeks.  
{icons}

## **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 25 °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 Animal Health UK Limited

## **14. MARKETING AUTHORISATION NUMBERS**

Vm 08327/5017

**15. BATCH NUMBER**

Lot {number}

**16. SPECIAL WARNING(S), IF NECESSARY**

**17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: Read package leaflet

**18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

POM-V ('Veterinary medicinal product subject to prescription')

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE FRONTLINE COMBO  
SPOT ON CAT {Blister card of 1 pipette}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

FRONTLINE COMBO SPOT-ON CAT

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each 0.5 ml pipette contains:

**Active substances:**

Fipronil	50.00 mg
(S)-methoprene	60.00 mg

**Excipients:**

Butylhydroxyanisole (E320).....	0.10 mg
Butylhydroxytoluene (E321).....	0.05 mg

FIPRONIL 10% w/v (S) METHOPRENE 12% 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**

0.5 ml

**4. TARGET SPECIES**

Cats  
Ferrets

**5. INDICATION(S)**

**For products not subject to veterinary prescription:**

Eliminates fleas.

Eliminates ticks.

Eliminates biting lice on your cat.

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 25°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 Animal Health UK Limited

## **14. MARKETING AUTHORISATION NUMBERS**

Vm 08327/5017

## **15. BATCH NUMBER**

Lot {number}

## **16. SPECIAL WARNING(S), IF NECESSARY**

## **17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: Read package leaflet

## **18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

POM-V ('Veterinary medicinal product subject to prescription')
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**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING  
UNITS FRONTLINE COMBO SPOT ON CAT {1 pipette}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

FRONTLINE COMBO

**2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE  
SUBSTANCES**

0.5 ml:  
FIPRONIL 50 mg  
(S)-METHOPRENE 60 mg

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

**5. 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]

**6. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS FRONTLINE  
COMBO SPOT ON CAT {Box of 3 pipettes: 1 blister of 3 pipettes, Box of 4  
pipettes: 1 blister of 4 pipettes and Box of 6 pipettes: 2 blisters of 3 pipettes}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

FRONTLINE COMBO CAT

**2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE  
SUBSTANCES**

Fipronil 50mg / (S) Methoprene 60mg

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

**PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET {Box of 3 pipettes,  
Box of 4 pipettes and Box of 6 pipettes}:**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Frontline Combo 50.00 mg / 60.00 mg spot-on solution for cat

**2. COMPOSITION**

Each 0.5 ml pipette contains:

**Active substances:**

Fipronil .....50.00 mg  
(S)-methoprene .....60.00 mg

**Excipients:**

Butylhydroxyanisole (E320) .....0.10 mg  
Butylhydroxytoluene (E321) .....0.05 mg

Clear amber spot-on solution.

**3. TARGET SPECIES**

Cats, Ferrets.

**4. INDICATIONS FOR USE**

In cats:

To be used against infestations with fleas, alone or in association with ticks and/or biting lice.

- Elimination of fleas (*Ctenocephalides* spp.). Insecticidal efficacy against new infestations with adult fleas persists for 4 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 six weeks after application.
- Elimination of ticks (*Ixodes ricinus*, *Dermacentor variabilis*, *Rhipicephalus sanguineus*). The product has a persistent acaricidal efficacy for up to 2 weeks against ticks (based on experimental data).
- Elimination of biting lice (*Felicola subrostratus*).

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

In ferrets:

To be used against infestations with fleas, alone or in association with ticks.

- Elimination of fleas (*Ctenocephalides* spp.). Insecticidal efficacy against new infestations with adult fleas persists for 4 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.

- Elimination of ticks (*Ixodes ricinus*). The product has a persistent acaricidal efficacy for 4 weeks against ticks (based on experimental data).

## 5. CONTRAINDICATIONS

In the absence of available data, the product should not be used on kittens less than 8 weeks old and/or weighing less than 1 kg. The product should not be used in ferrets less than 6 months 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.

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.

No data on the effect of bathing/shampooing on the efficacy of the product in cats and ferrets are available. However, based on information available for dogs shampooed as from 2 days after application of the product, it is not recommended to bath animals within 2 days after application of the product.

There may be an attachment of single 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.

### Special precautions for safe use in the target species:

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.

The potential toxicity of the product for kittens of less than 8 weeks of age in contact with a treated queen is not documented. Special care should be taken in this case.

### 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 plain 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:

See section “Special precautions for disposal”.

#### Pregnancy and lactation:

The veterinary medicinal product can be used during pregnancy in cats. For treatment during the lactating period, see above.

Use only according to benefit/risk assessment by a responsible veterinarian in ferrets.

#### Overdose:

Do not overdose.

The risk of experiencing adverse events may however increase when overdosing (see section 7 “Adverse events”).

#### Cats:

No adverse events were observed in target animal safety studies in cats and kittens aged 8 weeks and older and weighing about 1 kg treated once a month at five times the recommended dose for six consecutive months.

Itching may occur following treatment.

Overdose application of the product will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will disappear within 24 hours post application.

#### Ferrets:

In ferrets aged 6 months and older and treated once every 2 weeks for four treatments, at five times the recommended dose, body weight loss was observed in some animals.

## **7. ADVERSE EVENTS**

Cats and Ferrets:

**Very rare (<1 animal / 10,000 animals treated, including isolated reports):**

Application site reactions (skin scaling<sup>1</sup>, hair loss<sup>1</sup>, itching<sup>1</sup>, reddening<sup>1</sup>). Generalised itching or hair loss. Hypersalivation<sup>2</sup>, vomiting. Increased sensitivity to stimulation<sup>3</sup>, depression<sup>3</sup>, other nervous signs<sup>3</sup>.

<sup>1</sup> Transient

<sup>2</sup> If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.

<sup>3</sup> 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](mailto:adverse.events@vmd.gov.uk)

## **8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION**

Spot-on use.

Underdosing could result in ineffective use and may favour resistance development. The minimum dose is 5 mg/kg bw of fipronil and 6 mg/kg bw of (S)-methoprene, corresponding to one pipette of 0.5 ml per cat. In the absence of safety studies, the minimum treatment interval is 4 weeks.

The dose is 50 mg of fipronil and 60 mg of (S)-methoprene per ferret, corresponding to one pipette of 0.5 ml per ferret. The minimum treatment interval is 4 weeks.

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

## **9. ADVICE ON CORRECT ADMINISTRATION**

Method of administration: see outer packaging.

## **10. WITHDRAWAL PERIODS**

Not applicable.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Do not store above 25 °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.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. 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 08327/5017

Blister card of 1 x 0.5 ml pipette  
Box of 1 blister card of 3 x 0.5 ml pipettes  
Box of 1 blister card of 4 x 0.5 ml pipettes  
Box of 2 blister cards of 3 x 0.5 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](http://www.gov.uk).

## 16. CONTACT DETAILS

Marketing authorisation holder:  
Boehringer Ingelheim Animal Health UK Limited  
Ellesfield Avenue  
Bracknell  
Berkshire  
RG12 8YS  
United Kingdom

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.

**PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET FRONTLINE  
COMBO SPOT-ON CAT {Combined label and package leaflet for 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 50.00 mg / 60.00 mg spot-on solution for cat

**2. COMPOSITION**

Each 0.5 ml pipette contains:

**Active substances:**

Fipronil.....50.00 mg  
(S)-methoprene .....60.00 mg

**Excipients:**

Butylhydroxyanisole (E320).....0.10 mg  
Butylhydroxytoluene (E321) .....0.05 mg

FIPRONIL 10% w/v (S) METHOPRENE 12% 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**

0.5 ml

**4. TARGET SPECIES**

Cats  
Ferrets

**5. INDICATIONS FOR USE**

**Indications for use**

In cats:

To be used against infestations with fleas, alone or in association with ticks and/or biting lice.

- Elimination of fleas (*Ctenocephalides* spp.). Insecticidal efficacy against new infestations with adult fleas persists for 4 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 six weeks after application.

- Elimination of ticks (*Ixodes ricinus*, *Dermacentor variabilis*, *Rhipicephalus sanguineus*). The product has a persistent acaricidal efficacy for up to 2 weeks against ticks (based on experimental data).
- Elimination of biting lice (*Felicola subrostratus*).

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

In ferrets:

To be used against infestations with fleas, alone or in association with ticks.

- Elimination of fleas (*Ctenocephalides* spp.). Insecticidal efficacy against new infestations with adult fleas persists for 4 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.
- Elimination of ticks (*Ixodes ricinus*). The product has a persistent acaricidal efficacy for 4 weeks against ticks (based on experimental data).

## 6. CONTRAINDICATIONS

### Contraindications

In the absence of available data, the product should not be used on kittens less than 8 weeks old and/or weighing less than 1 kg. The product should not be used in ferrets less than 6 months 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.

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.

No data on the effect of bathing/shampooing on the efficacy of the product in cats and ferrets are available. However, based on information available for dogs shampooed as from 2 days after application of the product, it is not recommended to bath animals within 2 days after application of the product.

There may be an attachment of single 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.

Special precautions for safe use in the target species:

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.

The potential toxicity of the product for kittens of less than 8 weeks of age in contact with a treated queen is not documented. Special care should be taken in this case.

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 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:

See section "Special precautions for disposal".

Pregnancy and lactation:

The veterinary medicinal product can be used during pregnancy in cats. For treatment during the lactating period, see above.

Use only according to benefit/risk assessment by a responsible veterinarian in ferrets.

Overdose:

Do not overdose.

The risk of experiencing adverse events may however increase when overdosing (see Adverse Events).

Cats:

No adverse events were observed in target animal safety studies in cats and kittens aged 8 weeks and older and weighing about 1 kg treated once a month at five times the recommended dose for six consecutive months.

Itching may occur following treatment.

Overdose application of the product will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will disappear within 24 hours post application.

Ferrets:

In ferrets aged 6 months and older and treated once every 2 weeks for four treatments, at five times the recommended dose, body weight loss was observed in some animals.

## 8. ADVERSE EVENTS

### Adverse events

Cats and Ferrets:

#### **Very rare (<1 animal / 10,000 animals treated, including isolated reports):**

Application site reactions (skin scaling<sup>1</sup>, hair loss<sup>1</sup>, itching<sup>1</sup>, reddening<sup>1</sup>). Generalised itching or hair loss. Hypersalivation<sup>2</sup>, vomiting. Increased sensitivity to stimulation<sup>3</sup>, depression<sup>3</sup>, other nervous signs<sup>3</sup>.

<sup>1</sup> Transient

<sup>2</sup> If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.

<sup>3</sup> 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](mailto: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.

Underdosing could result in ineffective use and may favour resistance development.

Cats:

The minimum dose is 5 mg/kg bw of fipronil and 6 mg/kg bw of (S)-methoprene, corresponding to one pipette of 0.5 ml per cat.

Ferrets:

The dose is 50 mg of fipronil and 60 mg of (S)-methoprene per ferret, corresponding to one pipette of 0.5 ml per ferret.



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

## **10. ADVICE ON CORRECT ADMINISTRATION**

### **Advice on correct administration**

- 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 PERIOD(S)**

**Withdrawal periods:** not applicable.

## **12. SPECIAL STORAGE PRECAUTIONS**

Special storage precautions

Do not store above 25°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.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. 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 08327/5017

### Pack sizes

Blister card of 1 x 0.5 ml pipette

Box of 1 blister card of 3 x 0.5 ml pipettes

Box of 1 blister card of 4 x 0.5 ml pipettes

Box of 2 blister cards of 3 x 0.5 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](http://www.gov.uk).

## 17. CONTACT DETAILS

### Marketing authorisation holder:

Boehringer Ingelheim Animal Health UK Ltd  
Ellesfield Avenue  
Bracknell  
Berkshire  
RG12 8YS  
United Kingdom

### 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)**

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## **18. OTHER INFORMATION**

### **Other information**

Pharmacodynamics:

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

## **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: 31 March 2025