

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

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 SPOT-ON CAT

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.]

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Clear amber solution containing:

| | |
|----------------------------------|----------|
| Fipronil..... | 50.00 mg |
| (S)-methoprene | 60.00 mg |
| Butylhydroxyanisole (E320)..... | 0.10 mg |
| Butylhydroxytoluene (E321) | 0.05 mg |
| Excipient(s): q.s | 0.5 ml |

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

3 pipettes of 0.5 ml

4 pipettes of 0.5 ml

6 pipettes of 0.5 ml

5. TARGET SPECIES

Cats

Ferrets

6. INDICATION(S)

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.

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 0.5 ml per cat, corresponding to a minimum recommended dose of 5 mg/kg for fipronil and 6 mg/kg for (S)-methoprene, by topical application to the skin.

One pipette of 0.5 mL per ferret corresponding to a dose of 50 mg for fipronil and 60 mg for (S)-methoprene per ferret, by topical application to the skin.

8. WITHDRAWAL PERIOD

[NOT APPLICABLE]

9. SPECIAL WARNING(S), IF NECESSARY

For external use only.

Use during pregnancy and lactation

Frontline Combo Spot On Cat can be used during pregnancy in cats. For treatment during the lactating period, see section Precautions below.

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

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.

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.

Avoid the contact with the animal's eyes.

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.

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.

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 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.

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

Undesirable Effects

Do not overdose.

Among the very rare suspected adverse reactions, transient skin reactions on the application site (scaling, 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) or vomiting have also been observed after use.

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

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

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

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 inform your veterinary surgeon.

Alternatively, you can report via your national reporting system {national system details}.

Overdose

The risk of experiencing adverse effects may however increase with overdosing (see Undesirable Effects).

Cats

No undesirable effects 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.

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.

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

After accidental exposure the eye should be rinsed carefully with 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.

| |
|------------------------|
| 10. EXPIRY DATE |
|------------------------|

EXP {MM-YYYY}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°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 SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4210

17. MANUFACTURER’S BATCH NUMBER

BN {*number*}

Additional information:

[Manufacturer]

Boehringer Ingelheim Animal Health France SCS
4 chemin du Calquet

31000 Toulouse, France

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

FRONTLINE COMBO SPOT ON CAT

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 CAT

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.]

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition

| | |
|----------------------------------|----------|
| Fipronil..... | 50.00 mg |
| (S)-methoprene | 60.00 mg |
| Butylhydroxyanisole (E320)..... | 0.10 mg |
| Butylhydroxytoluene (E321) | 0.05 mg |
| Excipient(s): q.s | 0.5 ml |

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

3 pipettes of 0.5 ml
4 pipettes of 0.5 ml
6 pipettes of 0.5 ml

5. TARGET SPECIES

Cats
Ferrets

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

Do not store above 25°C

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 SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4210

17. MANUFACTURER’S BATCH NUMBER

BN {*number*}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

FRONTLINE COMBO SPOT ON CAT

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 CAT

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.]

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

FIPRONIL (S)-METHOPRENE

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

1 pipette of 0.5 ml

5. TARGET SPECIES

Cats

Ferrets

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

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.]

10. EXPIRY DATE

EXP {MM-YYYY}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C

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 SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4210

17. MANUFACTURER'S BATCH NUMBER

BN{*number*}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

FRONTLINE COMBO SPOT ON CAT

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 50 mg (S)-METHOPRENE 60 mg

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

0.5 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 cat and a ferret indicating the veterinary use]

[In Addition] Name of the MAH to be completed nationally

[Pictogram of a cat and a ferret indicating the target species]

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

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 CAT
FIPRONIL (S) METHOPRENE

2. NAME OF THE MARKETING AUTHORISATION HOLDER

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

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

0.5ml

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

B. PACKAGE LEAFLET

FRONTLINE COMBO SPOT-ON CAT

Box of 3 pipettes
Box of 4 pipettes
Box of 6 pipettes

*The leaflet described below applies to Case N°2 where a package leaflet is added in the packaging.
In Case N°1 no leaflet is needed.*

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

Marketing authorisation holder:
Boehringer Ingelheim Animal Health UK Ltd
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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTLINE COMBO SPOT-ON CAT
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. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Frontline Combo Spot On Cat is a clear amber solution containing:

- Fipronil 50.00 mg
- (S)-methoprene 60.00 mg
- Butylhydroxyanisole (E320) 0.10 mg
- Butylhydroxytoluene (E321) 0.05 mg

Excipient(s): q.s 0.5 ml.

4. INDICATION(S)

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 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.

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

6. ADVERSE REACTIONS

Do not overdose.

Among the very rare suspected adverse reactions, transient skin reactions on the application site (scaling, 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) or vomiting have also been observed after use.

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

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

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))

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

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Target species: Cats, Ferrets.

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

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

Dosage:

One pipette of 0.5 ml per cat. In the absence of safety studies, the minimum treatment interval is 4 weeks.

One pipette of 0.5 ml per ferret. The minimum treatment interval is 4 weeks.

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 25°C.

Store in the original package.

Keep out of the sight and reach 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.

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.

Avoid the contact with the animal's eyes.

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.

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.

Overdose

The risk of experiencing adverse effect may however increase with overdosing (see section 6 Adverse reactions).

Cats

No undesirable effects 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.

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.

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

After accidental exposure the eye should be rinsed carefully with 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.

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

September 2022

15. OTHER INFORMATION

Use during pregnancy, lactation or lay

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

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

Pharmacodynamic properties

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

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.

FRONTLINE COMBO SPOT-ON CAT
Blister card of 1 pipette

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

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

Marketing authorisation holder:

Boehringer Ingelheim Animal Health UK Ltd
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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTLINE COMBO SPOT-ON CAT

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

Frontline Combo Spot On Cat is a clear amber solution containing:

- Fipronil 50.00 mg
- (S)-methoprene 60.00 mg
- Butylhydroxyanisole (E320) 0.10 mg
- Butylhydroxytoluene (E321) 0.05 mg

Excipient(s): q.s 0.5 ml.

4. INDICATION(S)

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 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.

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

In the absence of safety studies, the minimum treatment interval is 4 weeks in cats and in ferrets.

6. ADVERSE REACTIONS

Do not overdose.

Among the very rare suspected adverse reactions, transient skin reactions on the application site (scaling, local hairloss, 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) or vomiting have also been observed after use.

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

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

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

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 inform your veterinary surgeon.

Alternatively, you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cat
Ferret

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

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

Dosage:

One pipette of 0.5 ml per cat corresponding to a minimum recommended dose of 5 mg/kg for fipronil and 6 mg/kg for (S)-methoprene.

One pipette of 0.5 mL per ferret corresponding to a dose of 50 mg for fipronil and 60 mg for (S)-methoprene per ferret, by topical application to the skin.

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.

10. WITHDRAWAL PERIOD

Not Applicable

11. SPECIAL STORAGE PRECAUTIONS

Storage

Do not store above 25°C.

Store in the original package.

Keep out of the sight and reach 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.

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.

Avoid the contact with the animal's eyes.

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.

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.

Overdose

The risk of experiencing adverse effect may however increase with overdosing (see Undesirable Effects).

Cats

No undesirable effects 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.

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.

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

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

Wash hands after use.

Treated animals should not be handled until the application site is dry, and children should not be allowed to play with treated animals until the application site is dry. It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals are not allowed to sleep with owners, especially children.

Do not smoke, drink or eat during application.

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

September 2022

15. OTHER INFORMATION

Use during pregnancy, lactation or lay

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

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

Pharmacodynamic properties

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

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.

ADDITIONAL INFORMATION TO APPEAR ON THE OUTER PACKAGE

FRONTLINE COMBO SPOT ON CAT

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

Box of 1 pipette (only highlighted text)

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}

Approved 17 November 2022

