

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

FRONTLINE PLUS SPOT-ON CAT

Box of 1 pipette (or 3 pipettes or 4 pipettes or 6 pipettes)

CASE N°1: *The text below corresponds to the cases where all the information of the package leaflet CAN be conveyed on the outer packaging and container.*

Consequently, in that case, no separate leaflet is provided in compliance with the current QRD Template.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTLINE PLUS SPOT-ON CAT [UK]

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

1 pipette of 0.5 ml
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.

- Treatment of flea infestations (*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.

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

In ferrets:

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

- Treatment of flea infestations (*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.
- Treatment of tick infestations (*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. Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette. Snap back the tip.

2-Part the coat on the back of the animal at the base of the neck in front of the shoulder blades until the skin is visible.

3-Place the tip of the pipette on the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin in one spot.



Dosage

One pipette of 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

The product can be used during pregnancy in cats. Consult your veterinary surgeon before using the product in lactating queens, or in pregnant or lactating jills.

Precautions

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

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

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 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.

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.

Animals should be weighed accurately prior to treatment.

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 and even mortality could occur. In absence of studies, the use of the product is not recommended in non-target species. In the absence of safety studies, the minimum treatment interval is 4 weeks.

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

Undesirable Effects

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 serious effects or other effects not mentioned here, please inform your veterinary surgeon.

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

Keep pipettes in original packaging until ready to use. In order to prevent children from getting access to used pipettes, dispose of used pipettes immediately.

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

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

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

After accidental exposure the eye should be rinsed carefully with 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.

Other precautions

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

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Store in the original package.

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

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

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

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

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

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

For animal treatment only.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4267

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

Additional information:

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

18. FURTHER INFORMATION

Blister card of 1 x 0.5 ml pipette
Box of 1 blister card of 1 x 0.5 ml pipette and two empty blister spaces
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.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

FRONTLINE PLUS SPOT-ON CAT

Box of 1 pipette (or 3 pipettes or 4 pipettes or 6 pipettes)

CASE N°2: *The text below corresponds to the cases where all the information of the package leaflet cannot be conveyed on the outer packaging and the container (for example for multilingual packaging). Consequently a package leaflet is added (see the corresponding template).*

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTLINE PLUS SPOT-ON 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

1 pipette of 0.5 ml
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. Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette. Snap back the tip.

2-Part the coat on the back of the animal at the base of the neck in front of the shoulder blades until the skin is visible.

3-Place the tip of the pipette on the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin in one spot.



8. WITHDRAWAL PERIOD

[NOT APPLICABLE]

9. SPECIAL WARNING(S), IF NECESSARY

For external use only.

Read the package leaflet before use.

User warnings

Keep pipettes in original packaging until ready to use. In order to prevent children from getting access to used pipettes, dispose of used pipettes immediately.

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

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

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

After accidental exposure the eye should be rinsed carefully with 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.

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

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store in the original package.
Do not store above 25°C.

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

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

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

For animal treatment only.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4267

17. MANUFACTURER’S BATCH NUMBER

Batch {number}

18. FURTHER INFORMATION

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

FRONTLINE PLUS 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 PLUS 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 for full instructions and for user and environmental precautions.

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Spot-on.

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

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

8. WITHDRAWAL PERIOD

[Not Applicable]

9. SPECIAL WARNING(S), IF NECESSARY

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

10. EXPIRY DATE

EXP {MM-YYYY}

11. SPECIAL STORAGE CONDITIONS

Store in the original package.
Do not store above 25°C.

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

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

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

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

For animal treatment only.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4267

17. MANUFACTURER’S BATCH NUMBER

BN{Number}

18. FURTHER INFORMATION

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

FRONTLINE PLUS 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 PLUS [UK]

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 PLUS SPOT-ON CAT

Box of 1 pipette: 1 blister of 1 pipette

Box of 3 pipettes: 1 blister of 3 pipettes

Box of 4 pipettes: 1 blister of 4 pipettes

Box of 6 pipettes : 2 blisters of 3 pipettes

The blister package is the same in both cases: the information below appears on the blister shell or on the blister cap of the blister package.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTLINE PLUS

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Limited

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

0.5 ml

FIPRONIL 10 % w/v METHOPRENE 12 % w/v

B. PACKAGE LEAFLET

**PACKAGE LEAFLET FOR:
FRONTLINE PLUS SPOT-ON CAT**

**Box of 1 pipette
Box of 3 pipettes
Box of 4 pipettes
Box of 6 pipettes**

The leaflet described below applies to Case N°2 where a package leaflet is added in the packaging.

In Case N°1 no leaflet is 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, Bracknell, RG12 8YS, UK

Manufacturer responsible for batch release:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTLINE PLUS SPOT-ON 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)

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.

- Treatment of flea infestations (*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.

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

In ferrets:

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

- Treatment of flea infestations (*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.
- Treatment of tick infestations (*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 and even mortality could occur. In absence of studies, the use of the product is not recommended in non-target species. 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.

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 serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

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 this veterinary medicinal product after the expiry date stated on the carton after EXP.

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

12. SPECIAL WARNING(S)

Precautions

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

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

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 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.

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. Animals should be weighed accurately prior to treatment.

User warnings

Keep pipettes in original packaging until ready to use. In order to prevent children from getting access to used pipettes, dispose of used pipettes immediately.

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

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

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

After accidental exposure the eye should be rinsed carefully with 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.

Other Precautions

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

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.

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

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2022

15. OTHER INFORMATION

Use during pregnancy, lactation or lay

The product can be used during pregnancy in cats. Consult your veterinary surgeon before using the product in lactating queens, or in pregnant or lactating jills.

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 1 x 0.5 ml pipette and two empty blister spaces

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.

AVM-GSL Vm 08327/4267

FRONTLINE PLUS SPOT-ON CAT
Blister card of 1 pipette

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

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

Marketing authorisation holder

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

Manufacturer responsible for batch release:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTLINE PLUS 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)

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.

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

In ferrets:

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

- Treatment of flea infestations (*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.
- Treatment of tick infestations (*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 and even mortality could occur. In absence of studies, the use of the product is not recommended in non-target species.

Do not use in cases 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 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 serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

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

1-Take the pipette out of its packaging.

Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette. Snap back the tip.

2-Part the coat on the back of the animal at the base of the neck in front of the shoulder blades until the skin is visible.

3-Place the tip of the pipette on the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin in one spot.



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 this veterinary medicinal product after the expiry date stated on the package after EXP.

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

12. SPECIAL WARNING(S)

Precautions

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

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

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 from 2 days after application of the product, it is not recommended to bath animals within 2 days after application of the product.

Avoid 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.

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.

Animals should be weighed accurately prior to treatment.

User Warnings

Keep pipettes in original packaging until ready to use. In order to prevent children from getting access to used pipettes, dispose of used pipettes immediately.

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

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

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

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

Wash hands after use.

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

Do not smoke, drink or eat during application.

Other Precautions

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

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.

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

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2022

15. OTHER INFORMATION

Use during pregnancy, lactation or lay

The product can be used during pregnancy in cats. Consult your veterinary surgeon before using the product in lactating queens, or in pregnant or lactating jills.

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 1 x 0.5 ml pipette and two empty blister spaces

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.

AVM-GSL Vm 08327/4267

ADDITIONAL INFORMATION TO APPEAR ON THE OUTER PACKAGE

FRONTLINE PLUS SPOT-ON CAT

Box of 1 pipette (or 3 pipettes or 4 pipettes or 6 pipettes)

Blister card of 1 pipette (only highlighted text)

What does this product do?

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

Kills fleas on your cat or ferret for 4 weeks.

Prevents the development of flea eggs, larvae and pupae for 6 weeks when used in cats.

Kills ticks on your cat for up to 2 weeks and on your ferret for up to 4 weeks.

Kills biting lice on your cat.

{icons}

How to treat a home infestation

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

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

For cats 8 weeks or older, weighing at least 1 kg and ferrets 6 months or older. Can be used on cats during pregnancy.

**Tick efficacy for up to 2 weeks in cats. Minimum treatment interval 4 weeks. Before every use, read the information on the inside of the box for full instructions and all warnings.

Approved 18 November 2022

