

PACKAGING – Frontline Spray 100ML

Packaging consists of one concertina label made up of a peel back outer label, a packaging leaflet, and an inner, immediate label in contact with the bottle. For the purposes of the QRD template these components have been listed separately.

PARTICULARS TO APPEAR ON OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frontline Spray 0.25% w/v Cutaneous Spray Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Fipronil 0.25% w/v

3. PHARMACEUTICAL FORM

Cutaneous Spray Solution

4. PACKAGE SIZE

100ml

5. TARGET SPECIES

For Dogs and Cats

6. INDICATION(S)

Kills Fleas, Ticks & Lice

7. METHOD AND ROUTES OF ADMINISTRATION

Delivers 0.5 ml spray per pump action. Contains approx. 8 treatments for a short haired, medium sized cat or small dog (4 kg).

DOSE RATE: 3-6ml/kg (6-12 pump actions per kg).

8. WITHDRAWAL PERIOD

9. SPECIAL WARNINGS, IF NECESSARY

For external use only.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Highly flammable. Protect from direct sunlight. For animal treatment only. Keep out of the sight and reach of children.

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

Disposal: read enclosed leaflet

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE
[Distribution category]

For animal treatment only.

NFA-VPS

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

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4113

17. MANUFACTURER’S BATCH NUMBER

18. ADDITIONAL INFORMATION

READ SAFETY WARNINGS BEFORE USE.

PEEL ARROW ON LABEL FOR FULL INSTRUCTIONS.

PARTICULARS TO APPEAR ON IMMEDIATE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frontline Spray 0.25% w/v Cutaneous Spray Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Fipronil 0.25% w/v

3. PHARMACEUTICAL FORM

Cutaneous Spray Solution

4. PACKAGE SIZE

100ml

5. TARGET SPECIES

For Dogs and Cats

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Kills Fleas, Ticks & Lice

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Delivers 0.5 ml spray per pump action. Contains approx. 8 treatments for a short haired, medium sized cat or small dog (4 kg).

DOSE RATE: 3-6ml/kg (6-12 pump actions per kg).

8. WITHDRAWAL PERIOD

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For external use only.

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16. MARKETING AUTHORISATION NUMBER

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17. MANUFACTURER’S BATCH NUMBER

18. ADDITIONAL INFORMATION

READ SAFETY WARNINGS BEFORE USE.

PARTICULARS TO APPEAR IN THE PACKAGE LEAFLET

Please also refer to “Particulars to Appear in the Outer Carton” as this forms the first page of the packaging 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 Spray 0.25% w/v Cutaneous Spray Solution

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Fipronil 0.25% w/v

100 ml Solution containing 0.25% w/v fipronil

4. INDICATION(S)

For the treatment and prevention of infestations by fleas (*Ctenocephalides* species) and ticks (*Ixodes* species).

Can be used as part of a treatment strategy for flea allergy dermatitis in dogs and cats where this has been previously diagnosed by a veterinary surgeon.

For the control of infestations with *Trichodectes canis* biting lice in dogs and *Felicola subrostratus* biting lice in cats.

5. CONTRAINDICATIONS

Do not use on sick (systemic diseases, fever...) or convalescent animals.

Do not use in rabbits, as adverse events and even death could occur.

6. ADVERSE REACTIONS

Among the extremely rare suspected adverse reactions, transient cutaneous reactions erythema, pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs), vomiting or respiratory signs have been observed after use.

7. TARGET SPECIES

For cats and small dogs

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

100ml pack

Each pump action delivers 0.5ml

DOSAGE: 6-12 pump actions per kg* depending on the length of the hair.

*equivalent to 3-6ml/kg

Method of administration: Spray the entire body of the animal, and apply from a distance of approximately 10-20 cm. Apply against the lay of the hair and make sure that the entire coat of the animal is dampened. Ruffle the coat, especially in long haired animals, so that the product penetrates down to the skin. For treatment of the head region, and when treating young or nervous pets, application may be carried out by spraying onto a gloved hand and rubbing the product into the coat. Allow to dry naturally. Do not towel dry.

Dosage: In order to dampen the coat down to the skin, depending on the length of the hair, apply 3 to 6 ml per kg bodyweight, (7.5 to 15 mg of active ingredient per kg bodyweight) i.e. 6 to 12 pump applications per kg bodyweight.

9. ADVICE ON CORRECT ADMINISTRATION

ANIMALS SHOULD BE WEIGHED ACCURATELY PRIOR TO TREATMENT

The treatment



Treat your pet in a well ventilated room. (If you are treating a dog, you may prefer to treat it outside). Put on a pair of PVC or nitrile gloves*.

* A waterproof apron is recommended to protect clothing, especially when treating a number of animals.



Check the spray pump by depressing the nozzle. It should release a cone of spray. Do not breathe spray.



Decide on a way to keep your pet relatively still. You may want to hold it yourself, or perhaps ask a friend. Putting a collar on your pet will help you to hold it more firmly.



Ruffle the pet's dry coat against the lay of the hair, in preparation for spraying.



Hold the dispenser vertically, 10-20 cm (4-7 inches) away from the coat, then apply the spray, *dampening with the spray right down to the skin*. A guide to the approximate number of pumps you will require can be found after these directions.



Don't forget to spray the underside, neck and feet. To get to the underside of a dog, encourage it to roll over or sit. If your pet is a cat, you may need to lift it to get to the underside.



To ensure coverage of the head region, spray the product onto your glove and rub gently around the face of your pet, avoiding the eyes and ears.



When treating puppies, kittens or nervous pets, you may prefer to use a glove to apply the product all over.



When your pet has been thoroughly covered, massage the coat all over, to make sure the spray gets right down to the skin. Let your pet dry naturally in a well ventilated area (*do not put your pet straight into a pet carrier*)*.

*** If you are treating several animals, ensure that the room is well ventilated between treatments and allow animals to dry in a separate, well ventilated room.**



Keep your pet away from fires, heat or surfaces likely to be affected by the alcohol spray until dry and for at least 30 minutes after treatment.



Do not eat, drink or smoke when applying the spray. Do not use the product if you or your pet have a known hypersensitivity to insecticides or to alcohol. Wash hands after use.

Your pet is now protected against ticks for up to 1 month and against fleas for up to 3 months if it is a dog, and up to 2 months if it is a cat. When used as part of a strategy for the treatment of flea allergy dermatitis, monthly applications to the allergic patient and to other cats and dogs in the household are recommended.

A PRACTICAL GUIDE TO TREATMENT WITH FRONTLINE Spray 100 ml

It is important to dampen the animal down to the skin with FRONTLINE SPRAY to ensure effective treatment. The table below provides examples of the approximate number of pumps you would need depending on weight and hair length.

ANIMALS SHOULD BE WEIGHED ACCURATELY PRIOR TO TREATMENT

Cats/Dogs weighing:	Short hair	Long hair
4kg	24 pumps	48 pumps
8kg	48 pumps	96 pumps

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children. For animal treatment only.

This veterinary medicinal product does not require any special temperature storage conditions. Highly flammable. Protect from direct sunlight.

12. SPECIAL WARNING(S)

For animal treatment only. For external use only. Do not spray on a naked flame or any incandescent material. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon. Do not overdose. The risk of experiencing adverse effects may increase when overdosing, so animals should always be treated with the correct dose according to bodyweight. Do not use simultaneously with other flea products which are applied directly onto the animal. It is important to make sure that animals do not lick each other following treatment. Do

not spray directly onto areas of broken skin. When treating infestations of parasites, all in-contact animals should be treated with an appropriate product at the same time. Keep treated animals away from fires, other sources of heat and surfaces likely to be affected by the alcohol spray for at least 30 minutes following spraying or until the fur is totally dry. Allow treated animals to dry in a well ventilated room. Do not confine animals in an enclosed space or pet carrier until the coat is totally dry. For optimum efficacy, it is not recommended to bathe or shampoo the animals in the 2 days prior to or following treatment with the product. (Refer also to the 'Further Information' section of this leaflet.) Laboratory studies did not reveal any teratogenic effect of fipronil in the rat and rabbit. The formulation is very well tolerated by puppies following treatment of the lactating bitch. Data are not available on treatment of pregnant queens or nursing queens. Fipronil may adversely affect aquatic organisms. Do not allow dogs to swim in ponds or other waterways for 2 days after treatment.

User Warnings. This product can cause mucous membrane and eye irritation. Therefore, contact between the product and the mouth and eyes should be avoided. Following accidental ocular exposure the eye(s) should be rinsed carefully with clean water. People with a known hypersensitivity to fipronil or any of the other ingredients should avoid contact with the product. Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water. Treated animals should not be handled until the fur is dry, and children should not be allowed to play with treated animals until the fur 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. Spray animals in the open air or in a well ventilated room. Do not breathe spray. Do not smoke, drink or eat during application. Wear PVC or nitrile gloves during treatment of animals. It is recommended to wear a waterproof apron for the protection of clothing. If clothing becomes heavily wetted with the product, it should be removed and washed before re-use. Dispose of gloves after use and then wash hands with soap and water. Wash splashes from skin with soap and water immediately. If irritation occurs, seek medical advice. People with known skin sensitivity or asthma may be particularly sensitive to the product. Do not use the product if you have previously experienced a reaction to it.

Treatment of Multiple Animals: Good ventilation is particularly important where several animals are to be treated. Treat multiple animals outside, or reduce the build up of vapour by removing the animals from the treatment room while the alcohol is evaporating and ensure that the treatment room is well ventilated between individual treatments. In addition, ensure that the drying room is well ventilated and avoid housing several recently treated animals within the same air space.

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

Dispose of used packaging in the household refuse. Unused product should be returned to the veterinary surgeon. Do not contaminate ponds, waterways or ditches with the product or empty containers

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Vm 08327/4113

NFA-VPS

PLEASE READ ALL OF THE FOLLOWING INSTRUCTIONS BEFORE USE.

A SINGLE TREATMENT WILL PROTECT YOUR DOG FOR UP TO 3 MONTHS AND YOUR CAT FOR UP TO 2 MONTHS AGAINST FLEAS, AND UP TO 1 MONTH AGAINST TICKS.

The following directions are designed to ensure that your pet receives the maximum benefit from FRONTLINE Spray.

YOUR QUESTIONS **ANSWERED...**

Q. How soon after treatment can my pet be handled?

A. As soon as the coat is dry. After this, treated pets may be safely handled.

Q. What if I bath my pet - Will FRONTLINE Spray wear off?

A. No. The product is resistant to wetting after treatment. Even shampooing pets up to 4 times in 2 months will not significantly decrease the product's effectiveness. However, bathing or shampooing your pet in the 48 hours before or after treatment with the product is not recommended.

Q. How often should I re-spray my pet?

A. FRONTLINE Spray will last for up to 3 months against fleas in dogs and up to 2 months in cats. It will also last for up to 1 month against ticks in dogs and cats. More regular treatment may be needed if your pet has a severe flea problem. When used as part of a strategy for the treatment of flea allergy dermatitis, monthly applications to the allergic patient and to other cats and dogs in the household are recommended. The product is safe to use every month if necessary.

Q. Do I still need to treat the environment for fleas?

A. Yes, initial treatment of the immature fleas in the environment should still be carried out (including washing your pets bedding, thorough vacuuming around the house and also treatment of bedding, carpets and soft furnishings with a suitable insecticide).

Q. Will FRONTLINE Spray prevent ticks attaching to my pet?

A. No, ticks may still attach but will be killed within the first 24-48 hours.

Q. What if my pet licks his coat, will this harm him?

A. After treating your pet encourage him not to lick his coat until it is dry. However, if licking does occur, a brief period of hypersalivation may be observed due mainly to the nature of the carrier but this is unlikely to cause your pet any harm as the product has a very high safety profile, even when ingested.

Q. Is FRONTLINE Spray safe to use on puppies and kittens?

A. Puppies and kittens may be safely treated from 2 days of age. **Allow litters to dry completely in a warm well ventilated area before returning them to their mother.**

Fipronil is a member of the phenylpyrazole family of broad spectrum, non-systemic, insecticides/acaricides, which acts by blocking the GABA receptor to kill the target parasite on contact. It exhibits insecticidal and acaricidal activity against fleas and ticks including *Rhipicephalus* species and *Ixodes* species, and may aid in the control of a number of ectoparasite species in dogs and cats including, *Neotrombicula autumnalis* (harvest mites), *Sarcoptes* species (mange mites) and *Cheyletiella* species (fur mites). Treatment with the product has been shown to result in a significant reduction in the incidence of flea allergy dermatitis in both dogs and cats. The product is active for up to 3 months against fleas in dogs and up to 2 months in cats depending on the environmental challenge. The product is active for up to 1 month against ticks in dogs and cats. Treatment of bedding, carpets and soft furnishings with a suitable insecticide will aid reduction in environmental challenge and maximise the duration of protection against re-infestation provided by the product. The alcohol carrier may have adverse effects on painted, varnished or other household surfaces or furnishings. The product is not suitable for direct treatment of the environment. Puppies and kittens from 2 days of age may be safely treated with the product. The product is active against *Ixodes* species including *Ixodes ricinus*, important as the vector of Lyme disease. There may be an attachment of single ticks. For this reason a transmission of infectious diseases cannot be completely excluded if conditions are unfavorable. In the absence of safety studies, the minimum treatment interval is 4 weeks. Bathing or shampooing up to four times in two months has been shown to have no significant effect on the residual efficacy of the product. Monthly treatment is recommended when more frequent shampooing is

carried out (Refer also to the “Warnings” section of this leaflet). In the absence of specific tolerance and efficacy data, the product is not recommended for the treatment of species other than cats and dogs. **Do not use in rabbits.**

PACKAGING – Frontline Spray 250ML

Packaging consists of one concertina label made up of a peel back outer label, a packaging leaflet, and an inner, immediate label in contact with the bottle. For the purposes of the QRD template these components have been listed separately.

PARTICULARS TO APPEAR ON OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frontline Spray 0.25% w/v Cutaneous Spray Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Fipronil 0.25% w/v

3. PHARMACEUTICAL FORM

Cutaneous Spray Solution

4. PACKAGE SIZE

250ml

5. TARGET SPECIES

For Dogs and Cats

6. INDICATION(S)

Kills Fleas, Ticks & Lice

7. METHOD AND ROUTES OF ADMINISTRATION

Delivers 1.5 ml spray per pump action. Contains approx. 4 treatments for a short haired, medium sized dog (20 kg).

DOSE RATE: 3-6ml/kg (2-4 pump actions per kg).

8. WITHDRAWAL PERIOD

9. SPECIAL WARNINGS, IF NECESSARY

For external use only.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Highly flammable. Protect from direct sunlight. For animal treatment only. Keep out of the sight and reach of children.

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

Disposal: read enclosed leaflet

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE
[Distribution category]

For animal treatment only.

NFA-VPS

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

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4113

17. MANUFACTURER’S BATCH NUMBER

18. ADDITIONAL INFORMATION

READ SAFETY WARNINGS BEFORE USE.

PEEL ARROW ON LABEL FOR FULL INSTRUCTIONS.

PARTICULARS TO APPEAR ON IMMEDIATE LABEL

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Vm 08327/4113

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18. ADDITIONAL INFORMATION

READ SAFETY WARNINGS BEFORE USE.

PARTICULARS TO APPEAR IN THE PACKAGE LEAFLET

Please also refer to “Particulars to Appear in the Outer Carton” as this forms the first page of the packaging 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 Spray 0.25% Cutaneous Spray Solution

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Fipronil 0.25% w/v

250 ml Solution containing 0.25% w/v fipronil

4. INDICATION(S)

For the treatment and prevention of infestations by fleas (*Ctenocephalides* species) and ticks (*Ixodes* species).

Can be used as part of a treatment strategy for flea allergy dermatitis in dogs and cats where this has been previously diagnosed by a veterinary surgeon.

For the control of infestations with *Trichodectes canis* biting lice in dogs and *Felicola subrostratus* biting lice in cats.

5. CONTRAINDICATIONS

Do not use on sick (systemic diseases, fever...) or convalescent animals.

Do not use in rabbits, as adverse events and even death could occur.

6. ADVERSE REACTIONS

Among the extremely rare suspected adverse reactions, transient cutaneous reactions erythema, pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs), vomiting or respiratory signs have been observed after use.

7. TARGET SPECIES

For Dogs and Cats

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

250ml pack

Each pump action delivers 1.5ml

DOSAGE: 2-4 pump actions per kg* depending on the length of the hair

(*equivalent to 3-6ml/kg)

Method of administration: Adjust the pump nozzle to the spray setting. Spray the entire body of the animal, and apply from a distance of approximately 10-20 cm. Apply against the lay of the hair and make sure that the entire coat of the animal is dampened. Ruffle the coat, especially in long haired animals, so that the product penetrates down to the skin. For treatment of the head region, and when treating young or nervous pets, application may be carried out by spraying onto a gloved hand and rubbing the product into the coat. Allow to dry naturally. Do not towel dry.

Dosage: In order to dampen the coat down to the skin, depending on the length of the hair, apply 3 to 6 ml per kg bodyweight, (7.5 to 15 mg of active ingredient per kg bodyweight) i.e. 2 to 4 pump applications per kg bodyweight.

9. ADVICE ON CORRECT ADMINISTRATION

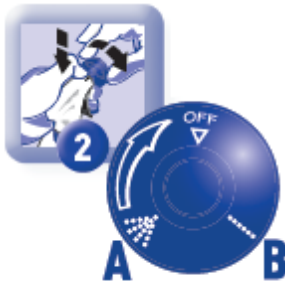
ANIMALS SHOULD BE WEIGHED ACCURATELY PRIOR TO TREATMENT

The treatment



Treat your pet in a well ventilated room. (If you are treating a dog, you may prefer to treat it outside). Put on a pair of PVC or nitrile gloves*.

* A waterproof apron is recommended to protect clothing, especially when treating a number of animals.



How to unlock the trigger pump:

Press down on the lock button located at the top of the trigger pump and, **AT THE SAME TIME**, turn the nozzle in the direction of the arrow.

A: Turn the nozzle a small distance in the direction of the arrow to obtain a spray.

B: If the nozzle is turned further a jet will be obtained.

The jet may be used to treat small areas where accuracy is required, like the feet. Do not breathe spray.



Decide on a way to keep your pet relatively still. You may want to hold it yourself, or perhaps ask a friend. Putting a collar on your pet will help you to hold it more firmly.



Ruffle the pet's dry coat against the lay of the hair, in preparation for spraying.



Hold the dispenser vertically, 10-20 cm (4-7 inches) away from the coat, then apply the spray, *dampening with the spray right down to the skin*. A guide to the approximate number of pumps you will require can be found after these directions.



Don't forget to spray the underside, neck and feet. To get to the underside of a dog, encourage it to roll over or sit.



To ensure coverage of the head region, spray the product onto your glove and rub gently around the face of your pet, avoiding the eyes and ears.



When treating young or nervous pets, you may prefer to use a glove or treat your pet all over.



When your pet has been thoroughly covered, massage the coat all over, to make sure the spray gets right down to the skin. Let your pet dry naturally in a well ventilated area.

**** If you are treating several animals, ensure that the room is well ventilated between treatments and allow animals to dry in a separate, well ventilated room.**



Keep your pet away from fires, heat or surfaces likely to be affected by the alcohol spray until dry and for at least 30 minutes after treatment.



Do not eat, drink or smoke when applying the spray. Do not use the product if you or your pet have a known hypersensitivity to insecticides or to alcohol. Wash hands after use.

Your pet is now protected against ticks for up to 1 month and against fleas for up to 3 months if it is a dog, and up to 2 months if it is a cat. When used as part of a strategy for the treatment of flea allergy dermatitis, monthly applications to the allergic patient and to other cats and dogs in the household are recommended

A PRACTICAL GUIDE TO TREATMENT WITH FRONTLINE Spray 250 ml

It is important to dampen the animal down to the skin with FRONTLINE SPRAY to ensure effective treatment. The table below provides examples of the approximate number of pumps you would need depending on weight and hair length.

ANIMALS SHOULD BE WEIGHED ACCURATELY PRIOR TO TREATMENT

Cats/Dogs weighing:	Short hair	Long hair
5kg	10 pumps	20 pumps
15kg	30 pumps	60 pumps
30kg	60 pumps	120 pumps

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children. For animal treatment only.

This veterinary medicinal product does not require any special temperature storage conditions. Highly flammable. Protect from direct sunlight.

12. SPECIAL WARNING(S)

For animal treatment only. For external use only. Do not spray on a naked flame or any incandescent material. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon. Do not overdose. The risk of experiencing adverse effects may increase when overdosing, so animals should always be treated with the correct dose according to bodyweight. Do not use simultaneously with other flea products which are applied directly onto the animal. It is important to make sure that animals do not lick each other following treatment. Do not spray directly onto areas of broken skin. When treating infestations of parasites, all in-contact animals should be treated with an appropriate product at the same time. Keep treated animals away from fires, other sources of heat and surfaces likely to be affected by the alcohol spray for at least 30 minutes following spraying or until the fur is totally dry. Allow treated animals to dry in a well ventilated room. Do not confine animals in an enclosed space or pet carrier until the coat is totally dry. For optimum efficacy, it is not recommended to bathe or shampoo the animals in the 2 days prior to or following treatment with the product. (Refer also to the 'Further Information' section of this leaflet.) Laboratory studies did not reveal any teratogenic effect of fipronil in the rat and rabbit. The formulation is very well tolerated by puppies following treatment of the lactating bitch. Data are not available on treatment of pregnant queens or nursing queens. Fipronil may adversely affect aquatic organisms. Do not allow dogs to swim in ponds or other waterways for 2 days after treatment.

User Warnings. This product can cause mucous membrane and eye irritation. Therefore, contact between the product and the mouth and eyes should be avoided. Following accidental ocular exposure the eye(s) should be rinsed carefully with clean water. People with a known hypersensitivity to fipronil or any of the other ingredients should avoid contact with the product. Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water. Treated animals should not be handled until the fur is dry, and children should not be allowed to play with treated animals until the fur 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. Spray animals in the open air or in a well ventilated room. Do not breathe spray. Do not smoke, drink or eat during application. Wear PVC or nitrile gloves during treatment of animals. It is recommended to wear a waterproof apron for the protection of clothing. If clothing becomes heavily wetted with the product, it should be removed and washed before re-use. Dispose of gloves after use and then wash hands with soap and water. Wash splashes from skin with soap and water immediately. If irritation occurs, seek medical advice. People with known skin sensitivity or asthma may be

particularly sensitive to the product. Do not use the product if you have previously experienced a reaction to it.

Treatment of Multiple Animals: Good ventilation is particularly important where several animals are to be treated. Treat multiple animals outside, or reduce the build up of vapour by removing the animals from the treatment room while the alcohol is evaporating and ensure that the treatment room is well ventilated between individual treatments. In addition, ensure that the drying room is well ventilated and avoid housing several recently treated animals within the same air space.

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

Dispose of used packaging in the household refuse. Unused product should be returned to the veterinary surgeon. Do not contaminate ponds, waterways or ditches with the product or empty containers.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Vm 08327/4113

NFA-VPS

PLEASE READ ALL OF THE FOLLOWING INSTRUCTIONS BEFORE USE.

A SINGLE TREATMENT WILL PROTECT YOUR DOG FOR UP TO 3 MONTHS AND YOUR CAT FOR UP TO 2 MONTHS AGAINST FLEAS, AND UP TO 1 MONTH AGAINST TICKS.

The following directions are designed to ensure that your pet receives the maximum benefit from FRONTLINE Spray.

YOUR QUESTIONS **ANSWERED...**

Q. How soon after treatment can my pet be handled?

A. As soon as the coat is dry. After this, treated pets may be safely handled.

Q. What if I bath my pet - Will FRONTLINE Spray wear off?

A. No. The product is resistant to wetting after treatment. Even shampooing pets up to 4 times in 2 months will not significantly decrease the product's effectiveness. However, bathing or shampooing your pet in the 48 hours before or after treatment with the product is not recommended.

Q. How often should I re-spray my pet?

A. FRONTLINE Spray will last for up to 3 months against fleas in dogs and up to 2 months in cats. It will also last for up to 1 month against ticks in dogs and cats. More regular treatment may be needed if your pet has a severe flea problem. When used as part of a strategy for the treatment of flea allergy dermatitis, monthly applications to the allergic patient and to other cats and dogs in the household are recommended. The product is safe to use every month if necessary.

Q. Do I still need to treat the environment for fleas?

A. Yes, initial treatment of the immature fleas in the environment should still be carried out (including washing your pets bedding, thorough vacuuming around the house and also treatment of bedding, carpets and soft furnishings with a suitable insecticide).

Q. Will FRONTLINE Spray prevent ticks attaching to my pet?

A. No, ticks may still attach but will be killed within the first 24-48 hours.

Q. What if my pet licks his coat, will this harm him?

A. After treating your pet encourage him not to lick his coat until it is dry. However, if licking does occur, a brief period of hypersalivation may be observed due mainly to the nature of the carrier but this is unlikely to cause your pet any harm as the product has a very high safety profile, even when ingested.

Q. Is FRONTLINE Spray safe to use on puppies and kittens?

A. Puppies and kittens may be safely treated from 2 days of age. **Allow litters to dry completely in a warm well ventilated area before returning them to their mother.**

Fipronil is a member of the phenylpyrazole family of broad spectrum, non-systemic, insecticides/acaricides, which acts by blocking the GABA receptor to kill the target parasite on contact. It exhibits insecticidal and acaricidal activity against fleas and ticks including *Rhipicephalus* species and *Ixodes* species, and may aid in the control of a number of ectoparasite species in dogs and cats including, *Neotrombicula autumnalis* (harvest mites), *Sarcoptes* species (mange mites) and *Cheyletiella* species (fur mites). Treatment with the product has been shown to result in a significant reduction in the incidence of flea allergy dermatitis in both dogs and cats. The product is active for up to 3 months against fleas in dogs and up to 2 months in cats depending on the environmental challenge. The product is active for up to 1 month against ticks in dogs and cats. Treatment of bedding, carpets and soft furnishings with a suitable insecticide will aid reduction in environmental challenge and maximise the duration of protection against re-infestation provided by the product. The alcohol carrier may have adverse effects on painted, varnished or other

household surfaces or furnishings. The product is not suitable for direct treatment of the environment. Puppies and kittens from 2 days of age may be safely treated with the product. The product is active against *Ixodes* species including *Ixodes ricinus*, important as the vector of Lyme disease. There may be an attachment of single ticks. For this reason a transmission of infectious diseases cannot be completely excluded if conditions are unfavorable. In the absence of safety studies, the minimum treatment interval is 4 weeks. Bathing or shampooing up to four times in two months has been shown to have no significant effect on the residual efficacy of the product. Monthly treatment is recommended when more frequent shampooing is carried out (Refer also to the “Warnings” section of this leaflet). In the absence of specific tolerance and efficacy data, the product is not recommended for the treatment of species other than cats and dogs. **Do not use in rabbits.**

PACKAGING – Frontline Spray 500ML

Packaging consists of one concertina label made up of a peel back outer label, a packaging leaflet, and an inner, immediate label in contact with the bottle. For the purposes of the QRD template these components have been listed separately.

PARTICULARS TO APPEAR ON OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frontline Spray 0.25% w/v Cutaneous Spray Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Fipronil 0.25% w/v

3. PHARMACEUTICAL FORM

Cutaneous Spray Solution

4. PACKAGE SIZE

500ml

5. TARGET SPECIES

For Dogs and Cats

6. INDICATION(S)

Kills Fleas, Ticks & Lice

7. METHOD AND ROUTES OF ADMINISTRATION

Delivers 1.5 ml spray per pump action. Contains approx. 8 treatments for a short haired, medium sized dog (20 kg).

DOSE RATE: 3-6ml/kg (2-4 pump actions per kg).

8. WITHDRAWAL PERIOD

9. SPECIAL WARNINGS, IF NECESSARY

For external use only.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Highly flammable. Protect from direct sunlight. For animal treatment only. Keep out of the sight and reach of children.

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

Disposal: read enclosed leaflet

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE
[Distribution category]

For animal treatment only.

NFA-VPS

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

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4113

17. MANUFACTURER’S BATCH NUMBER

18. ADDITIONAL INFORMATION

READ SAFETY WARNINGS BEFORE USE.

PEEL ARROW ON LABEL FOR FULL INSTRUCTIONS.

PARTICULARS TO APPEAR ON IMMEDIATE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frontline Spray 0.25% w/v Cutaneous Spray Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Fipronil 0.25% w/v

3. PHARMACEUTICAL FORM

Cutaneous Spray Solution

4. PACKAGE SIZE

500ml

5. TARGET SPECIES

For Dogs and Cats

6. INDICATION(S)

Kills Fleas, Ticks & Lice

7. METHOD AND ROUTES OF ADMINISTRATION

Delivers 1.5 ml spray per pump action. Contains approx. 8 treatments for a short haired, medium sized dog (20 kg).

DOSE RATE: 3-6ml/kg (2-4 pump actions per kg).

8. WITHDRAWAL PERIOD

9. SPECIAL WARNINGS, IF NECESSARY

For external use only.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Highly flammable. Protect from direct sunlight. For animal treatment only. Keep out of the sight and reach of children.

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

Disposal: read enclosed leaflet

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]

For animal treatment only.

NFA-VPS

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

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4113

17. MANUFACTURER’S BATCH NUMBER

18. ADDITIONAL INFORMATION

READ SAFETY WARNINGS BEFORE USE.

PARTICULARS TO APPEAR IN THE PACKAGE LEAFLET

Please also refer to “Particulars to Appear in the Outer Carton” as this forms the first page of the packaging 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 Spray 0.25% Cutaneous Spray Solution

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Fipronil 0.25% w/v

500 ml Solution containing 0.25% w/v fipronil

4. INDICATION(S)

For the treatment and prevention of infestations by fleas (*Ctenocephalides* species) and ticks (*Ixodes* species).

Can be used as part of a treatment strategy for flea allergy dermatitis in dogs and cats where this has been previously diagnosed by a veterinary surgeon.

For the control of infestations with *Trichodectes canis* biting lice in dogs and *Felicola subrostratus* biting lice in cats.

5. CONTRAINDICATIONS

Do not use on sick (systemic diseases, fever...) or convalescent animals.

Do not use in rabbits, as adverse events and even death could occur.

6. ADVERSE REACTIONS

Among the extremely rare suspected adverse reactions, transient cutaneous reactions erythema, pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs), vomiting or respiratory signs have been observed after use.

7. TARGET SPECIES

For Dogs and Cats

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

500ml pack

Each pump action delivers 1.5ml

DOSAGE: 2-4 pump actions per kg* depending on the length of the hair

(*equivalent to 3-6ml/kg)

Method of administration: Adjust the pump nozzle to the spray setting. Spray the entire body of the animal, and apply from a distance of approximately 10-20 cm. Apply against the lay of the hair and make sure that the entire coat of the animal is dampened. Ruffle the coat, especially in long haired animals, so that the product penetrates down to the skin. For treatment of the head region, and when treating young or nervous pets, application may be carried out by spraying onto a gloved hand and rubbing the product into the coat. Allow to dry naturally. Do not towel dry.

Dosage: In order to dampen the coat down to the skin, depending on the length of the hair, apply 3 to 6 ml per kg bodyweight, (7.5 to 15 mg of active ingredient per kg bodyweight) i.e. 2 to 4 pump applications per kg bodyweight.

9. ADVICE ON CORRECT ADMINISTRATION

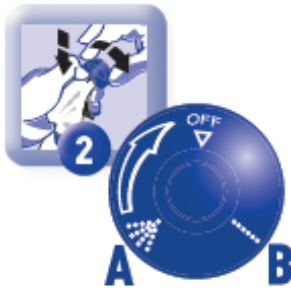
ANIMALS SHOULD BE WEIGHED ACCURATELY PRIOR TO TREATMENT

The treatment



Treat your pet in a well ventilated room. (If you are treating a dog, you may prefer to treat it outside). Put on a pair of PVC or nitrile gloves*.

* A waterproof apron is recommended to protect clothing, especially when treating a number of animals.



How to unlock the trigger pump:

Press down on the lock button located at the top of the trigger pump and, **AT THE SAME TIME**, turn the nozzle in the direction of the arrow.

A: Turn the nozzle a small distance in the direction of the arrow to obtain a spray.

B: If the nozzle is turned further a jet will be obtained.

The jet may be used to treat small areas where accuracy is required, like the feet. Do not breathe spray.



Decide on a way to keep your pet relatively still. You may want to hold it yourself, or perhaps ask a friend. Putting a collar on your pet will help you to hold it more firmly.



Ruffle the pet's dry coat against the lay of the hair, in preparation for spraying.



Hold the dispenser vertically, 10-20 cm (4-7 inches) away from the coat, then apply the spray, *dampening with the spray right down to the skin*. A guide to the approximate number of pumps you will require can be found after these directions.



Don't forget to spray the underside, neck and feet. To get to the underside of a dog, encourage it to roll over or sit.



To ensure coverage of the head region, spray the product onto your glove and rub gently around the face of your pet, avoiding the eyes and ears.



When treating young or nervous pets, you may prefer to use a glove or treat your pet all over.



When your pet has been thoroughly covered, massage the coat all over, to make sure the spray gets right down to the skin. Let your pet dry naturally in a well ventilated area (*do not put your pet straight into a pet carrier*)**.

**** If you are treating several animals, ensure that the room is well ventilated between treatments and allow animals to dry in a separate, well ventilated room.**



Keep your pet away from fires, heat or surfaces likely to be affected by the alcohol spray until dry and for at least 30 minutes after treatment.



Do not eat, drink or smoke when applying the spray. Do not use the product if you or your pet have a known hypersensitivity to insecticides or to alcohol. Wash hands after use.

Your pet is now protected against ticks for up to 1 month and against fleas for up to 3 months if it is a dog, and up to 2 months if it is a cat. When used as part of a strategy for the treatment of flea allergy dermatitis, monthly applications to the allergic patient and to other cats and dogs in the household are recommended.

A PRACTICAL GUIDE TO TREATMENT WITH FRONTLINE Spray 500 ml

It is important to dampen the animal down to the skin with FRONTLINE SPRAY to ensure effective treatment. The table below provides examples of the approximate number of pumps you would need depending on weight and hair length.

ANIMALS SHOULD BE WEIGHED ACCURATELY PRIOR TO TREATMENT

Cats/Dogs weighing:	Short hair	Long hair
5kg	10 pumps	20 pumps
15kg	30 pumps	60 pumps
30kg	60 pumps	120 pumps

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children. For animal treatment only.

This veterinary medicinal product does not require any special temperature storage conditions. Highly flammable. Protect from direct sunlight.

12. SPECIAL WARNING(S)

For animal treatment only. For external use only. Do not spray on a naked flame or any incandescent material. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon. Do not overdose. The risk of experiencing adverse effects may increase when overdosing, so animals should always be treated with the correct dose according to bodyweight. Do not use simultaneously with other flea products which are applied directly onto the animal. It is important to make sure that animals do not lick each other following treatment. Do not spray directly onto areas of broken skin. When treating infestations of parasites, all in-contact animals should be treated with an appropriate product at the same time. Keep treated animals away from fires, other sources of heat and surfaces likely to be affected by the alcohol spray for at least 30 minutes following spraying or until the fur is totally dry. Allow treated animals to dry in a well ventilated room. Do not confine animals in an enclosed space or pet carrier until the coat is totally dry. For optimum efficacy, it is not recommended to bathe or shampoo the animals in the 2 days prior to or following treatment with the product. (Refer also to the 'Further Information' section of this leaflet.) Laboratory studies did not reveal any teratogenic effect of fipronil in the rat and rabbit. The formulation is very well tolerated by puppies following treatment of the lactating bitch. Data are not available on treatment of pregnant queens or nursing queens. Fipronil may adversely affect aquatic organisms. Do not allow dogs to swim in ponds or other waterways for 2 days after treatment.

User Warnings. This product can cause mucous membrane and eye irritation. Therefore, contact between the product and the mouth and eyes should be avoided.

Following accidental ocular exposure the eye(s) should be rinsed carefully with clean water. People with a known hypersensitivity to fipronil or any of the other ingredients should avoid contact with the product. Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water. Treated animals should not be handled until the fur is dry, and children should not be allowed to play with treated animals until the fur 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. Spray animals in the open air or in a well ventilated room. Do not breathe spray. Do not smoke, drink or eat during application. Wear PVC or nitrile gloves during treatment of animals. It is recommended to wear a waterproof apron for the protection of clothing. If clothing becomes heavily wetted with the product, it should be removed and washed before re-use. Dispose of gloves after use and then wash hands with soap and water. Wash splashes from skin with soap and water immediately. If irritation occurs, seek medical advice. People with known skin sensitivity or asthma may be

particularly sensitive to the product. Do not use the product if you have previously experienced a reaction to it.

Treatment of Multiple Animals: Good ventilation is particularly important where several animals are to be treated. Treat multiple animals outside, or reduce the build up of vapour by removing the animals from the treatment room while the alcohol is evaporating and ensure that the treatment room is well ventilated between individual treatments. In addition, ensure that the drying room is well ventilated and avoid housing several recently treated animals within the same air space.

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15. OTHER INFORMATION

Vm 08327/4113

NFA-VPS

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The following directions are designed to ensure that your pet receives the maximum benefit from FRONTLINE Spray.

YOUR QUESTIONS ANSWERED...

Q. How soon after treatment can my pet be handled?

A. As soon as the coat is dry. After this, treated pets may be safely handled.

Q. What if I bath my pet - Will FRONTLINE Spray wear off?

A. No. The product is resistant to wetting after treatment. Even shampooing pets up to 4 times in 2 months will not significantly decrease the product's effectiveness. However, bathing or shampooing your pet in the 48 hours before or after treatment with the product is not recommended.

Q. How often should I re-spray my pet?

A. FRONTLINE Spray will last for up to 3 months against fleas in dogs and up to 2 months in cats. It will also last for up to 1 month against ticks in dogs and cats. More regular treatment may be needed if your pet has a severe flea problem. When used as part of a strategy for the treatment of flea allergy dermatitis, monthly applications to the allergic patient and to other cats and dogs in the household are recommended. The product is safe to use every month if necessary.

Q. Do I still need to treat the environment for fleas?

A. Yes, initial treatment of the immature fleas in the environment should still be carried out (including washing your pets bedding, thorough vacuuming around the house and also treatment of bedding, carpets and soft furnishings with a suitable insecticide).

Q. Will FRONTLINE Spray prevent ticks attaching to my pet?

A. No, ticks may still attach but will be killed within the first 24-48 hours.

Q. What if my pet licks his coat, will this harm him?

A. After treating your pet encourage him not to lick his coat until it is dry. However, if licking does occur, a brief period of hypersalivation may be observed due mainly to the nature of the carrier but this is unlikely to cause your pet any harm as the product has a very high safety profile, even when ingested.

Q. Is FRONTLINE Spray safe to use on puppies and kittens?

A. Puppies and kittens may be safely treated from 2 days of age. **Allow litters to dry completely in a warm well ventilated area before returning them to their mother.**

Fipronil is a member of the phenylpyrazole family of broad spectrum, non-systemic, insecticides/acaricides, which acts by blocking the GABA receptor to kill the target parasite on contact. It exhibits insecticidal and acaricidal activity against fleas and ticks including *Rhipicephalus* species and *Ixodes* species, and may aid in the control of a number of ectoparasite species in dogs and cats including, *Neotrombicula autumnalis* (harvest mites), *Sarcoptes* species (mange mites) and *Cheyletiella* species (fur mites). Treatment with the product has been shown to result in a significant reduction in the incidence of flea allergy dermatitis in both dogs and cats. The product is active for up to 3 months against fleas in dogs and up to 2 months in cats depending on the environmental challenge. The product is active for up to 4 weeks against ticks in dogs and cats. Treatment of bedding, carpets and soft furnishings with a suitable insecticide will aid reduction in environmental challenge and maximise the duration of protection against re-infestation provided by the product. The alcohol carrier may have adverse effects on painted, varnished or other

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Approved 28 May 2020

