

ANNEX III
LABELLING

PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGE

100 ml SPRAY

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETFLEA 2.5 mg/ml cutaneous spray, Solution for cats and dogs
Fipronil

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:

Fipronil 2.5 mg/ml

3. PHARMACEUTICAL FORM

Cutaneous spray, solution.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cats and dogs.

6. INDICATIONS

Treatment of flea infestation (*Ctenocephalides* spp.) in dogs and cats.

Treatment of tick infestation (*Ixodes ricinus*, *Rhipicephalus sanguineus*) in dogs and cats.

Treatment of biting lice infestations in dogs (*Trichodectes canis*) and cats (*Felicola subrostratus*).

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

Insecticidal efficacy against new infestations with adult fleas persists for up to 6 weeks in cats and 3 months in dogs, depending on environmental challenge.

The product has a persistent acaricidal efficacy for up to 4 weeks against ticks, depending on the level of environmental challenge.

7. CONTRAINDICATIONS

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

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

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

8. ADVERSE REACTIONS

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

Very rarely, transient cutaneous reactions (erythema, pruritus or alopecia) have been reported after use. Hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous symptoms), vomiting or respiratory signs have also been observed very rarely after use.

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.

9. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Route of administration:

Mechanical pump spray for external use only.

The pump delivers 0.5 ml (100 ml bottle) spray per pump.

Dosage:

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

This dosage can be achieved with 6 to 12 pump applications per kg bodyweight of the 100 ml presentation.

Depending on the coat length, the 100 ml presentation allows 4 to 8 treatments of a 4 kg cat or up to 3 treatments of a 10 kg dog.

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.



1 Adjust the nozzle



2 Spray against direction of hair growth, holding the animal



3 Large jet for back and sides, standing

4 Large jet for chest and belly, sitting or lying down



5 Narrow jet for paws and skin folds, standing

6 Put the product on a glove for the face

Properties:

The formulation contains a coating agent. Therefore, spraying builds up a film and makes the fur glossy.

10. ADVICE ON CORRECT ADMINISTRATION

Treatment schedule:

For optimal control of flea and/or tick infestation, the treatment schedule can be based on the local epidemiological situation.

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

Puppies and kittens from 2 days of age may be safely treated.

11. WITHDRAWAL PERIOD

Not applicable.

12. SPECIAL WARNINGS

Special warnings for each target species

Do not exceed the recommended dosage.

Avoid contact with the animal's eyes.

Do not spray directly onto areas of broken skin.

Allow treated animals to dry in a well ventilated room (see also section 4.5).

Do not confine animals in an enclosed space or pet carrier until the coat is totally dry.

In the absence of specific tolerance and efficacy data, the product is not recommended for the treatment of species other than cats and dogs.

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.

For optimum efficacy, it is not recommended to bathe or shampoo animals in the two days prior to or following treatment with the product. 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.

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.

For optimum control of flea problems in a multi-pet household, all dogs and cats in the household should be treated with a suitable insecticide.

Special precautions for use in animals

It is important to make sure that animals do not lick each other following treatment.

There may be an attachment of single ticks. For this reason transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.

The product is not suitable for direct treatment of the environment.

Keep treated animals away from fires or other sources of heat, and surfaces likely to be affected by the alcohol spray, for at least 30 minutes following spraying and until the fur is totally dry.

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

This product can cause mucous membrane and eye irritation. Therefore, contact between the product and the mouth or 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 ocular exposure the eye should be rinsed carefully with plain 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 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 sensitivity or asthma may be particularly sensitive to the product. Do not use 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.

Other precautions

Fipronil may adversely affect aquatic organisms. Dogs should not be allowed to swim in water courses for 2 days after application.

Use during pregnancy and lactation

Laboratory studies did not reveal any teratogenic effect of fipronil in the rat and rabbit. Fipronil is very well tolerated by puppies following treatment of the lactating bitch. Data is not available from specific studies during pregnancy in bitches, pregnancy in queens or in nursing queens. The safety of the veterinary medicinal product has not been established, therefore, use only in accordance with the risk/benefit assessment by the veterinarian.

Overdose

The risk of adverse effects may increase in cases of overdose.
Start an appropriate symptomatic treatment in case of overdosing.

13. EXPIRY DATE

<EXP {month/year}>. Do not use after the expiry date stated on the bottle.
Shelf-life after first use: 1 year. After first application, use by:...”

14. SPECIAL STORAGE CONDITIONS

Highly flammable. Do not store above 25°C. Protect from direct sunlight.

15. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS

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

Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

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

For animal treatment only.

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

Keep out of the sight and reach of children.

18. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder and batch release Manufacturer :

ALFAMED

13ème Rue – L.I.D.

06517 CARROS CEDEX

FRANCE

+ 33 (0)4 92 08 73 04

+ 33 (0)4 92 08 73 48

19. MARKETING AUTHORISATION NUMBER

Vm 17902/4025

20. MANUFACTURER'S BATCH NUMBER

<Batch> {number}

21. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

22. OTHER INFORMATION

Pack sizes :
100 ml, 250 ml, 500 ml.

Not all pack sizes may be marketed.

PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGE

250 ml SPRAY

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETFLEA 2.5 mg/ml cutaneous spray, Solution for cats and dogs
Fipronil

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:

Fipronil 2.5 mg/ml

3. PHARMACEUTICAL FORM

Cutaneous spray, solution.

4. PACKAGE SIZE

250 ml

5. TARGET SPECIES

Cats and dogs.

6. INDICATIONS

Treatment of flea infestation (*Ctenocephalides* spp.) in dogs and cats.

Treatment of tick infestation (*Ixodes ricinus*, *Rhipicephalus sanguineus*) in dogs and cats.

Treatment of biting lice infestations in dogs (*Trichodectes canis*) and cats (*Felicola subrostratus*).

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

Insecticidal efficacy against new infestations with adult fleas persists for up to 6 weeks in cats and 3 months in dogs, depending on environmental challenge.

The product has a persistent acaricidal efficacy for up to 4 weeks against ticks, depending on the level of environmental challenge.

7. CONTRAINDICATIONS

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

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

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

8. ADVERSE REACTIONS

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

Very rarely, transient cutaneous reactions (erythema, pruritus or alopecia) have been reported after use. Hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous symptoms), vomiting or respiratory signs have also been observed very rarely after use.

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.

9. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Route of administration:

Mechanical pump spray for external use only.

The pump delivers 1.5 ml (250 ml bottle) spray per pump.

Dosage:

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

This dosage can be achieved with 2 to 4 pump applications of the 250 ml presentation.

Depending on the coat length, the 250 ml presentation allows 2 to 4 treatments of a 20 kg dog.

Method of administration:

Adjust the pump nozzle to 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.



1 Adjust the nozzle



2 Spray against direction of hair growth, holding the animal



3 Large jet for back and sides, standing

4 Large jet for chest and belly, sitting or lying down



5 Narrow jet for paws and skin folds, standing

6 Put the product on a glove for the face

Properties:

The formulation contains a coating agent. Therefore, spraying builds up a film and makes the fur glossy.

10. ADVICE ON CORRECT ADMINISTRATION

Treatment schedule:

For optimal control of flea and/or tick infestation, the treatment schedule can be based on the local epidemiological situation.

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

Puppies and kittens from 2 days of age may be safely treated.

11. WITHDRAWAL PERIOD

Not applicable.

12. SPECIAL WARNINGS

Special warnings for each target species

Do not exceed the recommended dosage.

Avoid contact with the animal's eyes.

Do not spray directly onto areas of broken skin.

Allow treated animals to dry in a well ventilated room (see also section 4.5).

Do not confine animals in an enclosed space or pet carrier until the coat is totally dry.

In the absence of specific tolerance and efficacy data, the product is not recommended for the treatment of species other than cats and dogs.

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.

For optimum efficacy, it is not recommended to bathe or shampoo animals in the two days prior to or following treatment with the product. 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.

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.

For optimum control of flea problems in a multi-pet household, all dogs and cats in the household should be treated with a suitable insecticide.

Special precautions for use in animals

It is important to make sure that animals do not lick each other following treatment.

There may be an attachment of single ticks. For this reason transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.

The product is not suitable for direct treatment of the environment.

Keep treated animals away from fires or other sources of heat, and surfaces likely to be affected by the alcohol spray, for at least 30 minutes following spraying and until the fur is totally dry.

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

This product can cause mucous membrane and eye irritation. Therefore, contact between the product and the mouth or 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 ocular exposure the eye should be rinsed carefully with plain 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 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 sensitivity or asthma may be particularly sensitive to the product. Do not use 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.

Other precautions

Fipronil may adversely affect aquatic organisms. Dogs should not be allowed to swim in water courses for 2 days after application.

Use during pregnancy and lactation

Laboratory studies did not reveal any teratogenic effect of fipronil in the rat and rabbit. Fipronil is very well tolerated by puppies following treatment of the lactating bitch. Data is not available from specific studies during pregnancy in bitches, pregnancy in queens or in nursing queens. The safety of the veterinary medicinal product has not been established, therefore, use only in accordance with the risk/benefit assessment by the veterinarian.

Overdose

The risk of adverse effects may increase in cases of overdose.
Start an appropriate symptomatic treatment in case of overdosing.

13. EXPIRY DATE

<EXP {month/year}>. Do not use after the expiry date stated on the bottle.
Shelf-life after first use: 1 year. After first application, use by:...”

14. SPECIAL STORAGE CONDITIONS

Highly flammable. Do not store above 25°C. Protect from direct sunlight.

15. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS

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

Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

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

For animal treatment only.

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

Keep out of the sight and reach of children.

18. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder and batch release Manufacturer :

ALFAMED

13ème Rue – L.I.D.

06517 CARROS CEDEX

FRANCE

+ 33 (0)4 92 08 73 04

+ 33 (0)4 92 08 73 48

19. MARKETING AUTHORISATION NUMBER

Vm 17902/4025

20. MANUFACTURER’S BATCH NUMBER

<Batch> {number}

21. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

22. OTHER INFORMATION

Pack sizes :
100 ml, 250 ml, 500 ml.

Not all pack sizes may be marketed.

PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGE

500 ml SPRAY

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETFLEA 2.5 mg/ml cutaneous spray, Solution for cats and dogs
Fipronil

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:

Fipronil 2.5 mg/ml

3. PHARMACEUTICAL FORM

Cutaneous spray, solution.

4. PACKAGE SIZE

500 ml

5. TARGET SPECIES

Cats and dogs.

6. INDICATIONS

Treatment of flea infestation (*Ctenocephalides* spp.) in dogs and cats.

Treatment of tick infestation (*Ixodes ricinus*, *Rhipicephalus sanguineus*) in dogs and cats.

Treatment of biting lice infestations in dogs (*Trichodectes canis*) and cats (*Felicola subrostratus*).

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

Insecticidal efficacy against new infestations with adult fleas persists for up to 6 weeks in cats and 3 months in dogs, depending on environmental challenge.

The product has a persistent acaricidal efficacy for up to 4 weeks against ticks, depending on the level of environmental challenge.

7. CONTRAINDICATIONS

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

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

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

8. ADVERSE REACTIONS

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

Very rarely, transient cutaneous reactions (erythema, pruritus or alopecia) have been reported after use. Hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs), vomiting or respiratory signs have also been observed very rarely after use.

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.

9. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Route of administration:

Mechanical pump spray for external use only.

The pump delivers 3 ml (500 ml bottle) spray per pump.

Dosage:

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

This dosage can be achieved with 1 to 2 pump application(s) of the 500 ml presentation.

Depending on the coat length, the 500 ml presentation allows 2 to 4 treatments of a 40 kg dog.

Method of administration:

Adjust the pump nozzle to 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.



1 Adjust the nozzle



2 Spray against direction of hair growth, holding the animal



3 Large jet for back and sides, standing
4 Large jet for chest and belly, sitting or lying down



5 Narrow jet for paws and skin folds, standing
6 Put the product on a glove for the face

Properties:

The formulation contains a coating agent. Therefore, spraying builds up a film and makes the fur glossy.

10. ADVICE ON CORRECT ADMINISTRATION

Treatment schedule:

For optimal control of flea and/or tick infestation, the treatment schedule can be based on the local epidemiological situation.

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

Puppies and kittens from 2 days of age may be safely treated.

11. WITHDRAWAL PERIOD

Not applicable.

12. SPECIAL WARNINGS

Special warnings for each target species

Do not exceed the recommended dosage.

Avoid contact with the animal's eyes.

Do not spray directly onto areas of broken skin.

Allow treated animals to dry in a well ventilated room (see also section 4.5).

Do not confine animals in an enclosed space or pet carrier until the coat is totally dry.

In the absence of specific tolerance and efficacy data, the product is not recommended for the treatment of species other than cats and dogs.

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.

For optimum efficacy, it is not recommended to bathe or shampoo animals in the two days prior to or following treatment with the product. 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.

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.

For optimum control of flea problems in a multi-pet household, all dogs and cats in the household should be treated with a suitable insecticide.

Special precautions for use in animals

It is important to make sure that animals do not lick each other following treatment.

There may be an attachment of single ticks. For this reason transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.

The product is not suitable for direct treatment of the environment.

Keep treated animals away from fires or other sources of heat, and surfaces likely to be affected by the alcohol spray, for at least 30 minutes following spraying and until the fur is totally dry.

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

This product can cause mucous membrane and eye irritation. Therefore, contact between the product and the mouth or 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 ocular exposure the eye should be rinsed carefully with plain 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 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 sensitivity or asthma may be particularly sensitive to the product. Do not use 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.

Other precautions

Fipronil may adversely affect aquatic organisms. Dogs should not be allowed to swim in water courses for 2 days after application.

Use during pregnancy and lactation

Laboratory studies did not reveal any teratogenic effect of fipronil in the rat and rabbit. Fipronil is very well tolerated by puppies following treatment of the lactating bitch. Data is not available from specific studies during pregnancy in bitches, pregnancy in queens or in nursing queens. The safety of the veterinary medicinal product has not been established, therefore, use only in accordance with the risk/benefit assessment by the veterinarian.

Overdose

The risk of adverse effects may increase in cases of overdose.
Start an appropriate symptomatic treatment in case of overdosing.

13. EXPIRY DATE

<EXP {month/year}>. Do not use after the expiry date stated on the bottle.
Shelf-life after first use: 1 year. After first application, use by:..."

14. SPECIAL STORAGE CONDITIONS

Highly flammable. Do not store above 25°C. Protect from direct sunlight.

15. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS

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

Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

16. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

17. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

18. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder and batch release Manufacturer :
ALFAMED
13ème Rue – L.I.D.
06517 CARROS CEDEX
FRANCE
+ 33 (0)4 92 08 73 04
+ 33 (0)4 92 08 73 48

19. MARKETING AUTHORISATION NUMBER

Vm 17902/4025

20. MANUFACTURER'S BATCH NUMBER

<Batch> {number}

21. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

22. OTHER INFORMATION

Pack sizes :
100 ml, 250 ml, 500 ml.

Not all pack sizes may be marketed.

Approved: 15 February 2018

