ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Carton box of 3 pipettes
Carton box of 6 pipettes
Plastic card of 1 pipette

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frontline Tri-Act spot-on solution for dogs 20-40kg
Fipronil, permethrin

2. STATEMENT OF ACTIVE SUBSTANCES

fipronil 270.4 mg, permethrin 2019.2 mg

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

1 x 4 ml
3 x 4 ml
6 x 4 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Read the package leaflet before use.

(front of pack)
Kills fleas
Kills & repels ticks, mosquitoes, sandflies & biting flies*

(back of pack)
*For the treatment and prevention of flea (killing effect) and/or tick (killing and repellent effects) infestations where repellent activity is necessary against mosquitoes, sandflies and/or biting flies.

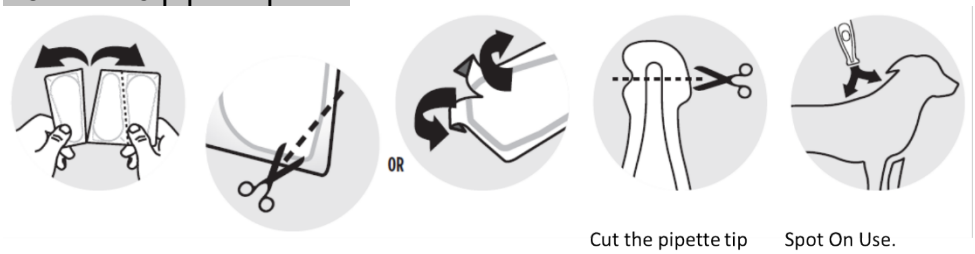
Kills FLEAS and prevents new infestations for 4 weeks
Kills & repels TICKS for 4 weeks**
Kills MOSQUITOES for 3 weeks and repels them for 4 weeks
Kills & repels SANDFLIES for 3 weeks
Kills & repels BITING FLIES (stable flies) for 5 weeks

**repels (*Ixodes ricinus, Rhipicephalus sanguineus)* ticks for 4 weeks after treatment, and repels *Dermacentor reticulatus* from 7 days up to 4 weeks after treatment.

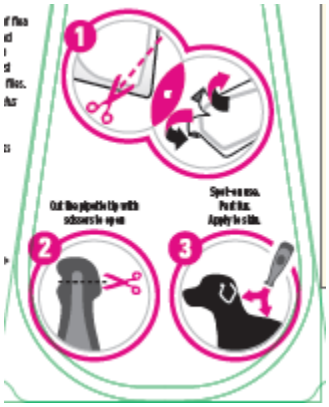
7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external use.
Spot-on use
Read the package leaflet before use.

X3 and X6 pipette packs



X1 pipette pack



8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in cats.

Do not use in rabbits.
Read the package leaflet before use

10. EXPIRY DATE

EXP {month/year}>

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use
Store in the original blister.
Do not store above 25°C.

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

Disposal: read package leaflet.

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 Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 08327/5083

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON BLISTERS
Blister foil
All presentations

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frontline Tri-Act [UK]
dogs 20-40kg

fipronil/permethrin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

BOEHRINGER INGELHEIM

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot (number)

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON PIPETTE
Pipette foil

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frontline Tri-Act
4 ml

2. NAME OF THE MARKETING AUTHORISATION HOLDER

BOEHRINGER INGELHEIM

3. EXPIRY DATE

EXP (month/year)

4. BATCH NUMBER

Lot (number)

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET
(Carton box of 3 or 6 pipettes)
Frontline Tri-Act spot-on solution for dogs 20-40 kg

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 Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom

Manufacturer for the batch release:
Boehringer Ingelheim Animal Health France SCS
4, Chemin du Calquet
31000 Toulouse
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frontline Tri-Act spot-on solution for dogs 20-40kg

fipronil, permethrin

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENT(S)

Spot-on solution.
Clear colourless to yellow-brown solution.

Active substances/ Excipients:
See section “dosage for each target species”.

4. INDICATIONS

In dogs:
For the treatment and prevention of flea (killing effect) and/or tick (killing and repellent effects) infestations where repellent activity is necessary against mosquitoes, sandflies and/or biting flies.

- Fleas

Treatment and prevention of *Ctenocephalides felis* flea infestations and prevention of *Ctenocephalides canis* flea infestations.. One treatment prevents new flea infestations for 4 weeks. The product can be used as part of a treatment strategy for flea allergy dermatitis where this has been previously diagnosed by a veterinarian.

- Ticks

Treatment and prevention of tick infestations (*Dermacentor reticulatus, Ixodes ricinus, Rhipicephalus sanguineus*). One treatment kills (*Dermacentor reticulatus, Ixodes ricinus, Rhipicephalus sanguineus*) and repels (*Ixodes ricinus, Rhipicephalus*

sanguineus) ticks for 4 weeks after treatment, and repels *Dermacentor reticulatus* from 7 days up to 4 weeks after treatment.

- Mosquitoes and sandflies

Repels (anti-feeding activity) sandflies (*Phlebotomus perniciosus*) for 3 weeks and mosquitoes *(Culex pipiens, Aedes albopictus*) for 4 weeks.
Kills sandflies (*Phlebotomus perniciosus)* and mosquitoes *(Aedes albopictus)* for 3 weeks.

- Biting flies (Stable flies)

Repels (anti-feeding activity) and kills stable flies (*Stomoxys calcitrans*) for 5 weeks.

5. CONTRAINDICATIONS

Do not use on sick or convalescent animals.
Do not use in cats or rabbits, as adverse reactions and even death could occur (see SPECIAL WARNINGS).
Do not use in cases of hypersensitivity to the active substances or to any of the excipients (see SPECIAL WARNINGS).

6. ADVERSE REACTIONS

Transient skin reactions at the application site (skin discolouration, local hair loss, itching, redness) and general itching, hair loss and erythema (redness) have been reported very rarely after use. Reversible nervous signs (increased sensitivity to stimulation, hyperactivity, muscle tremor, lethargy, ataxia (loss of coordination), other nervous signs) vomiting, anorexia (not eating) and hypersalivation have also been reported very rarely after use.
If licking of the application site occurs, transient hypersalivation and vomiting may be observed.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s)) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon. Alternatively, you can report via your national reporting system.

7. TARGET SPECIES

Dogs

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

For topical application to the skin (spot-on use).
The following table defines the pipette to be used according to the weight of the dog:

		Active ingredients		Excipients	
Frontline Tri-Act spot-on Solution for dogs	Volume of unit dose (ml)	Fipronil (mg)	Permethrin (mg)	Butylhydroxytoluene (E321) (mg)	N-methyl pyrrolidone (mg)
Medium dogs 10-20kg	2	135.2	1009.6	2.250	787.4
Large dogs 20-40kg	4	270.4	2019.2	4.500	1574.8
Extra large dogs 40-60kg	6	405.6	3028.8	6.750	2362.2
Dogs > 60 kg	Use the appropriate combination of previous pipettes				

Treatment schedule:
The use of the product should be based on a confirmed infestation or risk of infestation with fleas and/or ticks when repellent activity is also necessary against mosquitoes, sandflies and/or biting flies.
Depending on the ectoparasite challenge, repetition of the treatment might be indicated. In such instances, the interval between two treatments should be at least 4 weeks.

9. ADVICE ON CORRECT ADMINISTRATION

Select the appropriate pipette size for the weight of the dog. For dogs over 60 kg, use the appropriate combination of two pipette sizes that most closely matches the bodyweight.

The product should be applied in two out-of-reach spots so that the dog cannot lick the application site. These sites are at the base of the neck in front of the shoulder blades and the middle of the neck between the base of the skull and the shoulder blades.

Remove the blister card from the package and separate one blister. Remove the pipette by cutting along the dotted line with a pair of scissors or tearing open after folding the marked corner. Holding the pipette upright away from face and body, cut the pipette tip with scissors to open. Part the coat on the back of the dog until the skin is visible. Place the tip of the pipette on the skin. Squeeze the pipette, applying about half of the contents half way down the neck between the base of the skull and the shoulder blades. Repeat the application at the base of the neck in front of the shoulder blades to empty the pipette. For best results, ensure that the product is applied directly to the skin rather than on the hair.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in the original blister.
Do not store above 25°C.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after “EXP”. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Special warnings for each target species:
There may be an attachment of single ticks or bites by single mosquitoes or sandflies. For this reason, transmission of pathogens by these arthropods cannot be completely excluded if conditions are unfavorable. Single ticks may attach and detach within the first 24 hours after infestation and if ticks are present when the product is applied not all ticks may be killed within 48 hours after treatment.
The product remains effective against fleas when treated animals are immersed in water occasionally (e.g., swimming, bathing). However, dogs should not be allowed to swim or be shampooed within 48 hours after treatment. Avoid frequent swimming and shampooing of treated dogs as this may adversely affect maintenance of product effectiveness.
To reduce re-infestation from emergence of new fleas, it is recommended that all dogs in a household be treated. Other animals living in the same household should also be treated with a suitable product. To aid further in reducing environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developmental stages could be recommended.

Special precautions for use in animals:
In the absence of specific studies, the use of the product is not recommended in dogs younger than 8 weeks of age, or in dogs weighing less than 2 kg.
Care should be taken to avoid contact of the product with the dog’s eyes.
It is important to make sure that the product is applied to an area where the animal cannot lick it off and to make sure that other animals do not lick the treatment sites following application.
Animals should be weighed accurately prior to treatment.
Seek veterinary advice if the product is accidentally ingested or comes into contact with your dog’s eyes.
Do not use simultaneously with other products active against fleas, ticks or flies which are applied directly on to the animal.
Due to the presence of permethrin, the product can induce potentially fatal convulsions in cats. In case of accidental dermal (skin) exposure, wash the cat with shampoo or soap, and seek veterinary advice rapidly. To prevent cats from being accidentally exposed to the product, keep treated dogs away from cats until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog which has been treated with this product. In case of exposure of this type seek veterinary advice immediately.
Do not use in cats and rabbits.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
For animal treatment only.
This product can cause skin and eye irritation, therefore, avoid contact of the product with skin and eyes. Do not open the pipette near or towards the face. In case of ocular (eye) exposure or if eyes become irritated during administration, immediately flush the eyes with plenty of water. If ocular (eye) irritation persists, seek medical attention. In case of dermal (skin) exposure or if skin becomes irritated during administration, immediately wash the skin with plenty of soap and water. If skin irritation persists or recurs, seek medical attention.
People with known hypersensitivity to fipronil and/or permethrin should avoid contact with the product.
The product is harmful if swallowed. Avoid hand-to-mouth contact. Do not smoke, drink or eat during application. Wash hands after use. If swallowed rinse mouth and seek medical attention if you feel unwell.
Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant.
Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.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.
Keep the stored pipettes in the original blister and once used, the empty pipette should immediately be disposed of appropriately, preventing further access.

Other precautions
The product may adversely affect aquatic organisms. Treated dogs should not be allowed to enter surface water for 2 days after treatment.

Pregnancy and lactation
Laboratory studies using fipronil or permethrin have not produced any evidence of teratogenic (capable of causing embryonic or foetal malformation) or embryotoxic (capable of causing toxicity to the embryo) effects. The safety of the veterinary medicinal product has not been established in dogs during pregnancy and lactation or in animals intended for breeding.
Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.
Overdose (symptoms, emergency procedures, antidotes)
Safety has been assessed with up to 5 times the maximum dose in healthy adult dogs and in puppies. Transient side-effects such as mild nervous signs, vomiting and diarrhea may occur but are resolved without treatment within 1-2 days.
Animals should always be treated with the correct pipette size according to bodyweight.

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.
Do not contaminate ponds, waterways or ditches with the product or empty container.

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

15. OTHER INFORMATION

Fipronil is an insecticide and acaricide belonging to the phenylpyrazole family
Permethrin belongs to the Type I class of pyrethroids, which are acaricides and insecticides with repellent activity. Permethrin in the product provides repellent activity against sandflies (> 80% for 4 weeks), mosquitoes and ticks.
The product kills new infesting fleas (*C. felis, C. canis*) and ticks (*I. ricinus, R. sanguineus*) within 6 hours for a full month from 2 days after product application.
In one experimental study, the product was shown to indirectly reduce the risk of transmission of *Babesia canis* from infected *Dermacentor reticulatus* ticks from 7 days after application up to 4 weeks, thereby reducing the risk of canine babesiosis in treated dogs in this study.
In one experimental study, the product was shown to indirectly reduce the risk of transmission of *Ehrlichia canis* from infected *Rhipicephalus sanguineus* ticks, from 7 days after application up to 4 weeks, thereby reducing the risk of ehrlichiosis in treated dogs in this study.
However, the effectiveness of the product at reducing the transmission of infectious agents following natural exposure under field conditions has not been investigated.

Plastic card of 1 pipette containing 0.5 ml, 1 ml, 2 ml, 4 ml or 6 ml
Carton box of 3 or 6 pipettes containing 0.5 ml, 1 ml, 2 ml, 4 ml or 6 ml each
One size only per box.
Not all pack sizes may be marketed.

PACKAGE LEAFLET
(Plastic card of 1 pipette)
Frontline Tri-Act spot-on solution for dogs 20-40 kg

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 Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom

Manufacturer for the batch release:
Boehringer Ingelheim Animal Health France SCS
4, Chemin du Calquet
31000 Toulouse
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frontline Tri-Act spot-on solution for dogs 20-40kg

fipronil, permethrin

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENT(S)

Spot-on solution.
Clear colourless to yellow-brown solution.

Active substances/ Excipients:
See section “dosage for each target species”.

4. INDICATIONS

In dogs:
For the treatment and prevention of flea (killing effect) and/or tick (killing and repellent effects) infestations where repellent activity is necessary against mosquitoes, sandflies and/or biting flies.

- Fleas

Treatment and prevention of *Ctenocephalides felis* flea infestations and prevention of *Ctenocephalides canis* flea infestations. One treatment prevents new flea infestations for 4 weeks. The product can be used as part of a treatment strategy for flea allergy dermatitis where this has been previously diagnosed by a veterinarian.

- Ticks

Treatment and prevention of tick infestations (*Dermacentor reticulatus, Ixodes ricinus, Rhipicephalus sanguineus*). One treatment kills (*Dermacentor reticulatus, Ixodes ricinus, Rhipicephalus sanguineus*) and repels (*Ixodes ricinus, Rhipicephalus*

sanguineus) ticks for 4 weeks after treatment, and repels *Dermacentor reticulatus* from 7 days up to 4 weeks after treatment.

- Mosquitoes and sandflies

Repels (anti-feeding activity) sandflies (*Phlebotomus perniciosus*) for 3 weeks and mosquitoes *(Culex pipiens, Aedes albopictus)* for 4 weeks.
Kills sandflies (*Phlebotomus perniciosus)* and mosquitoes *(Aedes albopictus)* for 3 weeks.

- Biting Flies (Stable flies)

Repels (anti-feeding activity) and kills stable flies (*Stomoxys calcitrans*) for 5 weeks.

5. CONTRAINDICATIONS

Do not use on sick or convalescent animals.
Do not use in cats or rabbits, as adverse reactions and even death could occur (see SPECIAL WARNINGS).
Do not use in cases of hypersensitivity to the active substances or to any of the excipients (see SPECIAL WARNINGS).

6. ADVERSE REACTIONS

Transient skin reactions at the application site (skin discolouration, local hair loss, itching, redness) and general itching, hair loss and erythema (redness) have been reported very rarely after use. Reversible nervous signs (increased sensitivity to stimulation, hyperactivity, muscle tremor, lethargy, ataxia (loss of coordination), other nervous signs) vomiting, anorexia (not eating) and hypersalivation have also been reported very rarely after use.
If licking of the application site occurs transient hypersalivation and vomiting may be observed.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s)) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon. Alternatively, you can report via your national reporting system.

7. TARGET SPECIES

Dogs

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

For topical application to the skin (spot-on use).

		Active ingredients		Excipient	
Frontline Tri-Act spot-on Solution for dogs	*Volume of unit dose (ml)*	*Fipronil (mg)*	*Permethrin (mg)*	*Butylhydroxytoluene (E321) – (mg)*	*N-methyl pyrrolidone (mg)*
Large dogs 20-40kg	4	270.4	2019.2	4.500	1574.8

For dogs over 60 kg, use the appropriate combination of two pipette sizes that most closely matches the bodyweight.

Treatment schedule:

The use of the product should be based on a confirmed infestation or risk of infestation with fleas and/or ticks when repellent activity is also necessary against mosquitoes, sandflies and/or biting flies.
Depending on the ectoparasite challenge, repetition of the treatment might be indicated. In such instances, the interval between two treatments should be at least 4 weeks.

9. ADVICE ON CORRECT ADMINISTRATION

Select the appropriate pipette size(s) for the weight of the dog.

The product should be applied in two out-of-reach spots so that the dog cannot lick the application site. These sites are at the base of the neck in front of the shoulder blades and the middle of the neck between the base of the skull and the shoulder blades.
Remove the blister card from the package and separate one blister. Remove the pipette by cutting along the dotted line with a pair of scissors or tearing open after folding the marked corner. Holding the pipette upright away from face and body, cut the pipette tip with scissors to open. Part the coat on the back of the dog until the skin is visible. Place the tip of the pipette on the skin. Squeeze the pipette, applying about half of the contents half way down the neck between the base of the skull and the shoulder blades. Repeat the application at the base of the neck in front of the shoulder blades to empty the pipette. For best results, ensure that the product is applied directly to the skin rather than on the hair.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in the original blister.
Do not store above 25°C.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton label after “EXP”. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:
There may be an attachment of single ticks or bites by single mosquitoes or sandflies. For this reason, transmission of pathogens by these arthropods cannot be completely excluded if conditions are unfavorable. Single ticks may attach and detach within the first 24 hours after infestation and if ticks are present when the product is applied not all ticks may be killed within 48 hours after treatment.
The product remains effective against fleas when treated animals are immersed in water occasionally *(e.g.,* swimming, bathing). However, dogs should not be allowed to swim or be shampooed within 48 hours after treatment. Avoid frequent swimming or shampooing of treated dogs as this adversely affect maintenance of product effectiveness.
To reduce re-infestation from emergence of new fleas, it is recommended that all dogs in a household be treated. Other animals living in the same household should also be treated with a suitable product. To aid further in reducing environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developmental stages could be recommended.

Special precautions for use in animals:
In the absence of specific studies, the use of the product is not recommended in dogs younger than 8 weeks of age, or in dogs weighing less than 2 kg.
Care should be taken to avoid contact of the product with the dog’s eyes.
It is important to make sure that the product is applied to an area where the animal cannot lick it off and to make sure that other animals do not lick the treatment sites following application.
Animals should be weighed accurately prior to treatment.
Seek veterinary advice if the product is accidentally ingested or comes into contact with your dog’s eyes.
Do not use simultaneously with other products active against fleas, ticks or flies which are applied directly on to the animal.
Due to the presence of permethrin, the product can induce potentially fatal convulsions in cats. In case of accidental dermal (skin) exposure, wash the cat with shampoo or soap, and seek veterinary advice rapidly. To prevent cats from being accidentally exposed to the product, keep treated dogs away from cats until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog which has been treated with this product. In case of exposure of this type seek veterinary advice immediately.
Do not use in cats and rabbits

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
For animal treatment only.
This product can cause skin and eye irritation. Therefore, avoid contact of the product with skin and eyes. Do not open the pipette near or towards the face. In case of ocular (eye) exposure or if eyes become irritated during administration, immediately flush the eyes with plenty of water. If ocular (eye) irritation persists, seek medical attention. In case of dermal (skin) exposure or if skin becomes irritated during administration, immediately wash the skin with plenty of soap and water. If skin irritation persists or recurs, seek medical attention.
People with known hypersensitivity to fipronil and/or permethrin should avoid contact with the product.
The product is harmful if swallowed. Avoid hand-to-mouth contact. Do not smoke, drink or eat during application. Wash hands after use. If swallowed rinse mouth and seek medical attention if you feel unwell.
Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant.
Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.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.
Keep the stored pipettes in the original blister and once used, the empty pipette should immediately be disposed of appropriately, preventing further access.

Other precautions:
The product may adversely affect aquatic organisms. Treated dogs should not be allowed to enter surface water for 2 days after treatment.

Pregnancy and lactation
Laboratory studies using fipronil or permethrin have not produced any evidence of teratogenic (capable of causing embryonic or foetal malformation) or embryotoxic (capable of causing toxicity to the embryo) effects. The safety of the veterinary medicinal product has not been established in dogs during pregnancy and lactation or in animals intended for breeding.
Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects.Use only according to the benefit-risk assessment by the responsible veterinarian.

Overdose (symptoms, emergency procedures, antidotes)
Safety has been assessed with up to 5 times the maximum dose in healthy adult dogs and in puppies. Transient side-effects such as mild nervous signs, vomiting and diarrhea may occur but are resolved without treatment within 1-2 days.
Animals should always be treated with the correct pipette size according to bodyweight.

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.
Do not contaminate ponds, waterways or ditches with the product or empty container

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

15. OTHER INFORMATION

Fipronil is an insecticide and acaricide belonging to the phenylpyrazole family.
Permethrin belongs to the Type I class of pyrethroids, which are acaricides and insecticides with repellent activity. Permethrin in the product provides repellent activity against sandflies (> 80% for 4 weeks), mosquitoes and ticks.
The product kills new infesting fleas (*C. felis, C. canis*) and ticks (*I. ricinus, R. sanguineus*) within 6 hours for a full month from 2 days after product application.
In one experimental study, the product was shown to indirectly reduce the risk of transmission of *Babesia canis* from infected *Dermacentor reticulatus* ticks from 7 days after application up to 4 weeks, thereby reducing the risk of canine babesiosis in treated dogs in this study.
In one experimental study, the product was shown to indirectly reduce the risk of transmission of *Ehrlichia canis* from infected *Rhipicephalus sanguineus* ticks, from 7 days after application up to 4 weeks, thereby reducing the risk of ehrlichiosis in treated dogs in this study.
However, the effectiveness of the product at reducing the transmission of infectious agents following natural exposure under field conditions has not been investigated.

Plastic card of 1 pipette containing 0.5 ml, 1 ml, 2 ml, 4 ml or 6 ml
Carton box of 3 or 6 pipettes containing 0.5 ml, 1 ml, 2 ml, 4 ml or 6 ml each
One size only per box.
Not all pack sizes may be marketed.

Gavin Hall
Approved: 28 November 2025