<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fipnil Spot-on Solution Dog 268 mg

Fipronil

2. STATEMENT OF ACTIVE SUBSTANCES

Fipronil 268 mg

3. PHARMACEUTICAL FORM

Spot-on Solution

4. PACKAGE SIZE

2.68 ml.
1, 2, 3, 4 or 6 pipettes in a carton.

5. TARGET SPECIES

Dogs.

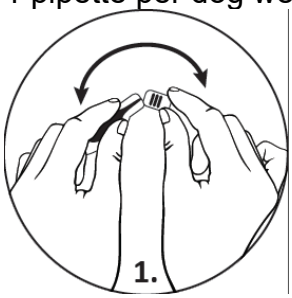
6. INDICATION(S)

Treatment of fleas and ticks.
Treatment of flea (*Ctenocephalides* spp.) and tick (*Rhipicephalus sanguineus* and *Ixodes ricinus*) infestations.

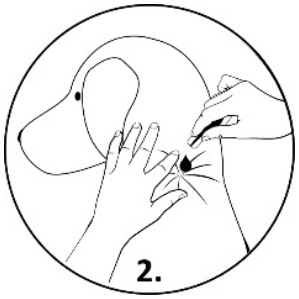
Insecticidal efficacy against new infestations with adult fleas persists for 8 weeks.
The product has a persistent acaricidal efficacy for 4 weeks against ticks (*Rhipicephalus sanguineus*, *Ixodes ricinus*, *Dermacentor reticulatus*).
If ticks of some species (*Dermacentor reticulatus*) are already present when the product is applied, all of the ticks may not be killed within the first 48 hours.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For Large Dogs 20 – 40 kg.
For topical administration.
Read the package leaflet before use.
1 pipette per dog weighing 20 – 40 kg bodyweight.



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



2. Part the pet's coat until the skin is visible.

3. Place the tip of the pipette directly against the bared skin and squeeze gently to empty its contents at two points along the dog's back, preferably at the base of the head and between the shoulder blades, emptying approximately half the volume at each site. Squeeze the pipette several times to ensure dosing is complete.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

User warnings

Please read before every use.

Keep stored pipettes in the original packaging until ready to use. In order to prevent children from getting access to used pipettes, dispose of used pipettes immediately. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or label to the physician.

This product can cause mucous membrane and eye irritation. Therefore, contact between the product and the mouth or eyes should be avoided.
In the case of accidental eye contact, immediately and thoroughly flush the eyes with water. If eye irritation persists seek medical advice and show the package leaflet or the label to the physician.
Do not smoke, drink or eat during application.

Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water. Wash hands after use.
People with a known hypersensitivity (allergy) to fipronil or any of the other ingredients should avoid contact with the product.
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 should not be allowed to sleep with owners, especially children.

Special precautions for use in animals
Do not use on puppies less than 2 months old and /or animals weighing less than 20 kg.
Do not use on sick (e.g. systemic diseases, fever…) or convalescent animals.
Do not use on animals with known hypersensitivity to the active substance or to any of the excipients.
Do not use in rabbits, as adverse reactions and even death could occur.
This product is specifically developed for dogs. Do not use in cats, as this could lead to overdosing.

Environmental Warnings:
Fipronil may adversely affect aquatic organisms. Dogs should not be allowed to swim in watercourses for 2 days after application.

10. EXPIRY DATE

EXP {month/year}

Discard any open pipettes.

11. SPECIAL STORAGE CONDITIONS

Do not use after expiry date.

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

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

Fipronil may adversely affect aquatic organisms. Dispose of empty packaging and any remaining product in accordance with the local requirements.

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

For animal treatment only.

AVM - GSL

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

EU Pharmaceuticals Ltd
37 Geraldine Road
London
SW18 2NR
UK

16. MARKETING AUTHORISATION NUMBER

Vm 39787/4006

17. MANUFACTURER'S BATCH NUMBER

BN{number}

	Month 1:	Month 2:	Month 3:
Date:			

PARTICULARS TO APPEAR ON THE SMALL IMMEDIATE PACKAGE UNIT

{2.68 ml pipette}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fipnil 268 mg

2. STATEMENT OF ACTIVE SUBSTANCES

Fipronil 268 mg

3. PACKAGE SIZE

2.68 ml

4. ROUTE OF ADMINISTRATION

Spot-on

5. EXPIRY DATE

EXP {month/year}

6. MANUFACTURER'S BATCH NUMBER

Lot{number}

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SACHET

{SACHET FOIL TEXT}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fipnil Spot-on Solution *Dog L 268 mg*

2. NAME OF THE MARKETING AUTHORISATION HOLDER

EU Pharmaceuticals Ltd.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {month/year}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For Animal Treatment Only.

Note: Text in italics will be overprinted at the time of production.

PACKAGE LEAFLET

Fipnil Spot-on Solution Dog 67 mg

Fipnil Spot-on Solution Dog 134 mg

Fipnil Spot-on Solution Dog 268 mg

Fipnil Spot-on Solution for Dog 402 mg

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

Marketing Authorisation holder:

EU Pharmaceuticals Ltd

37 Geraldine Road

London

SW18 2NR

UK

Manufacturing Authorisation Holder responsible for batch release:

Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fipnil Spot-on Solution Dog 67 mg

Fipnil Spot-on Solution Dog 134 mg

Fipnil Spot-on Solution Dog 268 mg

Fipnil Spot-on Solution Dog 402 mg

Fipronil

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

Each 0.67 ml/1.34 ml/2.68 ml/4.02 ml pipette contains:

Fipronil 67 mg/134 mg/268 mg/402 mg

Butylhydroxyanisole E320 0.134 mg/0.268 mg/0.536 mg/0.804 mg
Butylhydroxytoluene E321 0.067 mg/0.134 mg/0.268 mg/0.402 mg
Clear, pale amber solution.

4. INDICATION(S)

Treatment of flea (*Ctenocephalides* spp.) and tick (*Rhipicephalus sanguineus* and *Ixodes ricinus*) infestations.

Insecticidal efficacy against new infestations with adult fleas persists for 8 weeks.
The product has a persistent acaricidal efficacy for 4 weeks against ticks (*Rhipicephalus sanguineus*, *Ixodes ricinus*, *Dermacentor reticulatus*).
If ticks of some species (*Dermacentor reticulatus*) are already present when the product is applied, all of the ticks may not be killed within the first 48 hours.

5. CONTRAINDICATIONS

Do not use on puppies less than 2 months old.

Fipnil Spot-on Solution Dog 67 mg: Do not use on animals weighing less than 2 kg.
Fipnil Spot-on Solution Dog 134 mg: Do not use on animals weighing less than 10 kg.
Fipnil Spot-on Solution Dog 268 mg: Do not use on animals weighing less than 20 kg.
Fipnil Spot-on Solution Dog 402 mg: Do not use on animals weighing less than 40 kg.

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

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

This product is specifically developed for dogs. Do not use in cats, as this could lead to overdosing.

Do not use on animals with known hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

If licking occurs, a brief period of hypersalivation (excessive production of saliva) may be observed due mainly to the nature of the ingredients.
Among the extremely rare suspected adverse reactions, temporary skin reactions on the application site (skin discoloration, local hair loss, pruritus (itching), erythema (redness)) and general pruritus (itching) or hair loss have been reported after use.
Exceptionally, hypersalivation, reversible neurologic symptoms (hyperesthesia (abnormal increased sensitivity to any stimulus), depression, nervous symptoms), vomiting or respiratory symptoms have been observed after use.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

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

7. TARGET SPECIES

Dogs

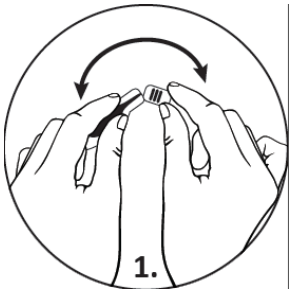
8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Route of administration and dosage:
External use only.
Dose according to the animal's bodyweight as follows:

Bodyweight	Dose
2 – 10 kg	1 pipette of Fipnil Spot-on Solution Dog 67 mg
10 – 20 kg	1 pipette of Fipnil Spot-on Solution Dog 134 mg
20 – 40 kg	1 pipette of Fipnil Spot-on Solution Dog 268 mg
40 – 60 kg	1 pipette of Fipnil Spot-on Solution Dog 402 mg
Over 60 kg	2 pipettes of Fipnil Spot-on Solution Dog 268 mg

Method of administration:

Administer by topical application to the skin as follows:



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

2. Part the pet's coat until the skin is visible.

3. Place the tip of the pipette directly against the bared skin and squeeze gently to empty its contents at two points along the dog's back, preferably at the base of the head and between the shoulder blades, emptying approximately half the volume at each site. Squeeze the pipette several times to ensure dosing is complete.

Application of the solution as directed minimises the possibility that the animal will lick the solution off.

Care should be taken to avoid excessive wetting of the hair with the product since this will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will usually disappear within 24 - 48 hours post application. Crystals may be seen on the hair and slight scaling may occur within 24 – 48 hours after application.

Treatment schedule:
For optimal control of flea and/or tick infestation the treatment schedule can be based on the local epidemiological situation.
The minimum interval between two treatments is 4 weeks.
Discard any opened pipettes.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure administration of a correct dose, body weight should be determined as accurately as possible
Application of the solution as directed minimises the possibility that the animal will lick the solution off.
Care should be taken to avoid excessive wetting of the hair with the product since this will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will usually disappear within 24 - 48 hours post application. Crystals may be seen on the hair and slight scaling may occur within 24 – 48 hours after application.

10. WITHDRAWAL PERIOD

N/A

11. SPECIAL STORAGE PRECAUTIONS

Do not use after expiry date stated on the label.
Do not store above 25°C. Store in a dry place in the original package.
Keep out of the sight and reach of children.

12. SPECIAL WARNING(S)

Special warnings for each target species
Avoid frequent swimming or shampooing the animal because the maintenance of effectiveness of the product in these cases has not been tested.

The product does not prevent ticks from attaching to the animals. If the animal has been treated prior to exposure to the ticks, the ticks will be killed in the first 24 – 48 hours after attachment. This will usually be prior to engorgement, minimising but not excluding the risk of transmission of diseases. Once dead, ticks will often drop off the animal, but any remaining ticks may be removed with a gentle pull.

Fleas from pets often infest the animal's basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated, in case of massive infestation and at the beginning of the control measures, with a suitable insecticide and vacuumed regularly.
For optimal control of flea infestation 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
Avoid contact with the animal's eyes. In the case of accidental eye contact, immediately and thoroughly flush the eyes with water.

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

Do not apply the product on wounds or damaged skin.

Pregnancy and lactation:
Laboratory studies using fipronil have not shown any evidence of teratogenic or embryotoxic effect. Studies have not been carried out with this product in pregnant and lactating bitches. Use in pregnancy and lactation only in accordance with professional veterinary advice and a benefit/risk assessment.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose (symptoms, emergency procedures, antidotes):
Animals should be weighed accurately prior to treatment. Do not overdose. The risk of adverse effects may increase when overdosing, so animals should always be treated with the correct pipette size according to bodyweight.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Keep pipettes in original packaging until ready to use.
This product can cause mucous membrane and eye irritation. Therefore, contact between the product and the mouth or eyes should be avoided.
In the case of accidental eye contact, immediately and thoroughly flush the eyes with water. If eye irritation persists seek medical advice and show the package leaflet or the label to the physician.
Do not smoke, drink or eat during application.

Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water. Wash hands after use.
Ingestion of the product is harmful. Prevent children getting access to the pipettes and discard the used pipettes immediately after applying the product. In case of accidental ingestion of product seek medical advice immediately and show the package leaflet or label to the physician.
People with a known hypersensitivity to fipronil or any of the other ingredients should avoid contact with the product.
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 should not be allowed to sleep with owners, especially children.

Environmental Warning:
Fipronil may adversely affect aquatic organisms. Dogs should not be allowed to swim in watercourses for 2 days after application.

Other precautions:
The product may have adverse effects on painted, varnished or other household surfaces or furnishings.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2021

15. OTHER INFORMATION

Each pipette is enclosed in sachet foil.

1, 2, 3, 4 or 6 pipettes in cartons.

Not all pack sizes may be marketed.

For animal treatment only.

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Approved: 24/09/21