

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flea & Tick Treatment 402 mg spot-on solution for very large dogs
Fipronil

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 Treatment / 2 Treatments / 3 Treatments / 6 Treatments

Each pipette contains 402 mg Fipronil.

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

1 pipette
2 pipettes
3 pipettes
6 pipettes

5. TARGET SPECIES

For very large dogs (40 – 60 kg)

Do not use this product on puppies of less than 2 months of age. **Weigh the dog first** and ensure that the correct size of pipette is used based on the weight of the dog. Each pipette in this pack would treat one dog weighing 40-60 kg. Do not use on dogs weighing less than 40 kg.

6. INDICATION(S)

Against fleas and ticks

Flea & Tick Treatment 402 mg spot-on solution for very large dogs is for killing fleas (*Ctenocephalides* spp.) and ticks (*Dermacentor variabilis* and *Rhipicephalus sanguineus*) on your dog. Applied at the base of the neck and between the shoulders, each treatment provides protection against fleas for up to 6 weeks and protects against *Dermacentor variabilis* ticks for up to 4 weeks and *Rhipicephalus sanguineus* ticks for up to 3 weeks.

This product does not prevent ticks from attaching to dogs but ticks will usually die within 48 hours. However, some ticks may still be present after 48 hours.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

DIRECTION FOR USE:



1. If applicable, separate one of the blisters from the blister strip. This helps to avoid accidental opening of the adjacent blister package in order to protect the still unopened pipettes from exposure to humidity. Open the blister with scissors. To avoid damaging of the pipette cut along the line marked with a scissors icon. Carefully peel back the foil from the cut off end and withdraw the pipette



2. Hold the pipette upright. Tap lightly to ensure the entire liquid contents are within the main body of the pipette. Bend the upper border strip backwards. Then the pipette can be set aside, if necessary. To open the pipette snap off the top of the pipette along the scored line



3. Part your dog's hair coat until the skin is visible. Place the tip of the pipette on the skin and squeeze several times to empty its content completely and directly onto the skin in one or two spots. Avoid applying onto the fur since this will cause a sticky appearance at the treatment site. Application of the solution near the base of the head minimizes the possibility that the animal will lick the solution off. Do not allow recently treated dogs to lick each other.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

PLEASE READ BEFORE EVERY USE

User Safety

- This product can cause mucous membrane and eye irritation. Avoid contact of the product with mouth and eyes. Should the product come into contact with the eyes, rinse thoroughly at once with water. If the eye irritation persists, seek medical help at once and show the package insert or label to the doctor.
- Avoid contact with the skin. Should the product come into contact with the skin, wash immediately with soap and water.
- Wash hands after use.
- Do not eat, drink or smoke during application.

- People with known hypersensitivity (allergy) to Fipronil or one of the other ingredients should avoid contact with the product.
- Treated animals should not be handled until the application site is dry. Children should not play with treated animals until the application site is dry. Therefore animals should not be treated during the day but during the early evening. Recently treated animals should not be allowed to sleep with owners, especially children.
- Keep stored pipettes in original packaging until ready for use. Dispose of used pipettes immediately in order to prevent children getting access to used pipettes.



DO NOT USE ON RABBITS

EFFECTIVE FLEA CONTROL

Regular treatment of all cats and dogs in the home together with regular vacuuming of your pet's bedding and resting areas is needed to protect your pet and home from fleas. At the beginning of flea control measures and if there is an existing and heavy infestation in the home, the home should be treated with an approved home flea product.

Read the enclosed package leaflet before use for full instructions and all warnings, including user warnings.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store in the original package.

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

Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container. Dispose of empty packaging and any remaining product in the household refuse.

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

For animal treatment only. For external use only.

Do not use if you know that your pet has a hypersensitivity to Fipronil or any of the other ingredient.

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

Perrigo Pharma International D.A.C.
Treasury Building
Grand Canal Street Lower
Dublin 2
Ireland

Distributed by: Galpharm International Limited,
Elmhirst Park, Middle Field Road, Barnsley,
South Yorkshire, S75 4LS, U.K.

Galpharm Petcare logo.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 16804/4002

AVM-GSL

17. MANUFACTURER’S BATCH NUMBER

Batch number

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flea & Tick Treatment 402 mg spot-on-solution for very large dogs
Fipronil

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Perrigo Pharma International D.A.C.

Galpharm Petcare Logo

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON PIPETTES

Pipette

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flea & Tick Treatment 402 mg spot-on solution for very large dogs Fipronil

2. EXPIRY DATE

EXP

3. BATCH NUMBER

Lot

4. Other

Topical use

For animal treatment only

Galpharm Petcare Logo

PACKAGE LEAFLET

Flea & Tick Treatment 100 mg/ml

Spot-on solution for small, medium, large and very large dogs

Flea & Tick Treatment spot-on solution for dogs is for killing fleas (*Ctenocephalides* spp.) and ticks (*Dermacentor variabilis* and *Rhipicephalus sanguineus*) on your dog. Applied at the base of the neck and between the shoulders, each treatment provides protection against fleas for up to 6 weeks and protects against *Dermacentor variabilis* ticks for up to 4 weeks and *Rhipicephalus sanguineus* ticks for up to 3 weeks. Fleas are killed within 48 hours.

This product does not prevent ticks from attaching to dogs but ticks will usually die within 48 hours. However, some ticks may still be present after 48 hours.

To safeguard your health and that of your dog please read this leaflet carefully before you apply the product to your dog.

If you need any help or advice on flea control for your pets:

Call us: 0044 (0) 113 244 1400

Write to us: Rosemont Pharmaceuticals Ltd. Braithwaite Street, Leeds LS11 9XE UK

Email us at: Pharmacovigilance@perrigouk.com

How should I use Flea & Tick Treatment spot-on solution?

Use one pipette per dog, applied to the skin as directed. For dogs over 60 kg use two pipettes of Flea & Tick Treatment 268 mg spot-on solution for large dogs.

Check that your dog is at least 2 months old **AND** that their weight falls within the weight range detailed on the front of the pack purchased.

The correct pipette size is shown in the table below.

DOG SIZE	PRODUCT	TREATMENT
2-10 kg	Flea & Tick Treatment 67 mg spot-on solution for small dogs	Use one 0.67 ml pipette
10-20 kg	Flea & Tick Treatment 134 mg spot-on solution for medium dogs	Use one 1.34 ml pipette
20-40 kg	Flea & Tick Treatment 268 mg spot-on solution for large dogs	Use one 2.68 ml pipette
40-60 kg	Flea & Tick Treatment 402 mg spot-on	Use one

	solution for very large dogs	4.02 ml pipette
Over 60 kg	Flea & Tick Treatment 268 mg spot-on solution for large dogs	Use two 2.68 ml pipettes Flea & Tick Treatment 268 mg spot-on solution for large dogs



1. If applicable, separate one of the blisters from the blister strip. This helps to avoid accidental opening of the adjacent blister package in order to protect the still unopened pipettes from exposure to humidity. Open the blister with scissors. To avoid damaging of the pipette cut along the line marked with a scissors icon. Carefully peel back the foil from the cut off end and withdraw the pipette



2. Hold the pipette upright. Tap lightly to ensure the entire liquid contents are within the main body of the pipette. Bend the upper border strip backwards. Then the pipette can be set aside, if necessary. To open the pipette snap off the top of the pipette along the scored line



3. Part your dog's hair coat until the skin is visible. Place the tip of the pipette on the skin and squeeze several times to empty its content completely and directly onto the skin in one or two spots. Avoid applying onto the fur since this will cause a sticky appearance at the treatment site. Application of the solution near the base of the head minimizes the possibility that the animal will lick the solution off. Do not allow recently treated cats to lick each other.

Do not use on puppies less than 2 months of age. **Weigh the dog first** and ensure that correct product is used for the weight of the dog.

Avoid excessive wetting of the hair with the product since this will cause a sticky appearance of hair at the treatment site.

Bathing and intensive wetting of the coat should be avoided for the first 2 days following administration of the product. Shampooing with a medicated shampoo, followed by thorough drying, 1 to 2 hours before treatment application and bathing once weekly over a period of 6 weeks, has been shown not to affect the efficacy of this veterinary medicinal product against fleas.

If licking of product occurs, a brief period of hypersalivation (drooling) may be observed.

On extremely rare occasions transient skin reactions at the application site (such as scaling, local hair loss, itching, reddening) or more widely across the animal (such as general pruritus or alopecia) have been reported.

Hypersalivation, reversible neurological signs (such as hyperaesthesia, depression, nervous signs), vomiting or respiratory signs have been reported exceptionally after product use.

Is Flea & Tick Treatment all I need?


Regular treatment of all cats and dogs in the home together with regular vacuuming of your pet's bedding and resting areas is needed to protect your pet and home from fleas and ticks. At the beginning of flea control measures and if there is an existing and heavy infestation in the home, the home should be treated with an approved home flea product.

How often should I use Flea & Tick Treatment?

This product provides protection from fleas for 6 weeks and protects against ticks for up to 4 weeks

The minimum interval between two treatments should be not less than 4 weeks.

For Safe Use

- Do not use on puppies less than 2 months old or weighing less than 2 kg.
- Do not use if you or your dog has a known hypersensitivity to Fipronil or any of the other ingredients.
- This product has been developed specifically for dogs. Do not use on cats as this could lead to overdosing.
- Do not allow recently treated animals to lick each other.
- Only apply the product as instructed so that your pet cannot lick it off.
- Take care to ensure that the liquid in the pipette does not come into contact with the pet's eyes or mouth. If it does come into contact, wash it off quickly and thoroughly. If necessary seek veterinary advice.
- Do not apply to any area of your dog's skin that is damaged (scratched, reddened, broken).
- Do not use on sick or convalescent animals.
- Not recommended for use in pregnant or nursing dogs. Consult your veterinary surgeon for advice.
- If signs of flea or tick infestation persist or appear during the period when the product is expected to be effective, consult a veterinary surgeon.
- Do not use at the same time as other flea products which are applied directly onto the dog's skin.
-  Do not use on rabbits as adverse drug reactions and even death may occur!

- The safety of the product has not been investigated in studies where overdose or repeated dosing were used due to the well-known safety profile of the active substance and other ingredients. However, the risk of adverse effects is likely to increase with overdoing. Therefore, animals should always be treated with the correct pipette size according to body weight.
- There may be attachment of some ticks. For this reason transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.

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

User Safety – Please Read Before Every Use

- This product can cause mucous membrane and eye irritation. Avoid contact of the product with mouth and eyes. Should the product come into contact with the eyes, rinse thoroughly at once with water. If the eye irritation persists, seek medical help at once and show the package insert or label to the doctor.
- Avoid contact with the skin. Should the product come into contact with the skin, wash immediately with soap and water.
- Wash hands after use.
- Do not eat, drink or smoke during application.
- People with known hypersensitivity (allergy) to Fipronil or one of the other ingredients should avoid contact with the product.
- Treated animals should not be handled until the application site is dry. Children should not play with treated animals until the application site is dry. Therefore animals should not be treated during the day but during the early evening. Recently treated animals should not be allowed to sleep with owners, especially children.
- Keep stored pipettes in original packaging until ready for use. Dispose of used pipettes immediately in order to prevent children getting access to used pipettes.

General Precautions

- Keep out of the sight and reach of children.
- For animal treatment only.
- For external use only.
- Do not use after the expiry date which is printed on the blister and pipette after EXP. The date refers to the last day of that month.
- Fipronil may adversely affect aquatic organisms. Dogs should not be allowed to swim in water courses for 2 days after application

- The product may have adverse effects on painted, varnished or other household surfaces or furnishing. Allow application site to dry before permitting contact with these materials

Storage and Disposal

- This veterinary medicinal product does not require any special storage conditions
- Store in the original package
- Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container. Dispose of empty packaging and any remaining product in the household refuse.

Contents

Each pipette is individually packed in a blister.

PRODUCT	DOG SIZE	TREATMENT	CONTENTS		
			Active Substance	Excipients (other ingredients)	
			Fipronil	Butylhydroxyanisole (E 320)	Butylhydroxytoluene (E 321)
Flea & Tick Treatment 67 mg spot-on solution for small dogs Vm 16804/4004	2-10 kg	Use one 0.67 ml pipette	67 mg	0.134 mg	0.067 mg
Flea & Tick Treatment 134 mg spot-on solution for medium dogs Vm 16804/4000	10-20 kg	Use one 1.34 ml pipette	134 mg	0.268 mg	0.134 mg
Flea & Tick Treatment 268 mg spot-on solution for large dogs Vm 16804/4001	20-40 kg	Use one 2.68 ml pipette	268 mg	0.536 mg	0.268 mg
For dogs over 60 kg use two pipettes of Flea & Tick Treatment 268 mg spot-on solution for large dogs					
Flea & Tick Treatment 402 mg spot-on solution for very large dogs Vm 16804/4002	40-60 kg	Use one 4.02 ml pipette	402 mg	0.804 mg	0.402 mg

Authorised pack sizes:
Cartons of 1, 2, 3 or 6 pipettes

Not all pack sizes maybe marketed.

AVM-GSL

MA Holder: Perrigo Pharma International D.A.C.

Treasury Building, Grand Canal Street Lower, Dublin 2, Ireland

Manufacturer responsible for Batch release:

Klocke Verpackungs-Service GmbH, Max-Becker-Str. 6, 76356 Weingarten,
Germany

The leaflet was last revised in July 2016.

Approved: 21/04/2017

A handwritten signature in black ink, appearing to read 'J. Long'.