PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton of 1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90, 120 or 150 pipettes containing 4.02 ml pipettes

Flick 402 mg Spot-On Solution for Very Large Dogs Fipronil

Ticks and Fleas For dogs weighing 40-60 kg.

What is in this medicine?

Each pipette of product contains 402 mg of the active ingredient Fipronil. Other ingredients are Butylhydroxyanisole (E320) [0.804 mg per pipette] and Butylhydroxyanisole (E321) [0.402 mg per pipette].

What is this medicine used for?

Flick is for the treatment of infestations by fleas (*Ctenocephalides felis*). The product shows immediate effect against fleas and persistent activity against new infestations for up to 8 weeks.

Persistent activity has been demonstrated for up to 2 weeks against the Sheep Tick (*Ixodes ricinus*), for up to 3 weeks against the Brown Dog Tick (*Rhipicephalus sanguineus*) and up to 4 weeks against the Cow Tick (*Dermacentor reticulatus*). If ticks are present at the time of treatment, it may take up to one week for all to be killed.

How do I use this medicine?

Read the package leaflet before use. For External Use Only. Do no remove the pipette from the sachet until use.

How should this medicine be stored?

Keep out of the sight and reach of children.

This medicinal product does not require any special temperature storage conditions. Store in the original container in order to protect from light and moisture.

User Safety Warnings

Treated animals should not be handled or played with until the application site has dried. Therefore evening application is recommended. Treated dogs should not be allowed to sleep with owners, especially children.

This product can cause mucous membrane and eye irritation. Do not get the product on your skin or in your eyes or mouth. If skin contact does occur wash it off quickly with soap and water. In the case of accidental eye contact, immediately and thoroughly flush the eyes with clean water. If eye irritation continues seek medical advice and show the package leaflet to the doctor.

Do not eat, drink or smoke while using this product.

Wash hands thoroughly after use.

People with a known hypersensitivity (allergy) to fipronil or any of the other ingredients should avoid contact with the product.

For animal treatment only.

Keep out of the sight and reach of children.

For **Special Warnings** and **Disposal** – read the package leaflet before use.

The Marketing Authorisation Holder is:
Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

Distributor:
Lintbells Limited
West Barn
Fairclough Hall Farm
Halls Green
Weston
Hitchin
Hertfordshire
SG4 7DP

Vm 02000/4323

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EXP: mm/yyyy

BN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMEMEDIATE PACKAGING UNITS

Sachet for 4.02 ml pipette/blister

Flick 402 mg Spot-On Solution for Very Large Dogs Fipronil

One pipette contains 402 mg of the active ingredient Fipronil.

For application directly to the skin.

4.02 ml

BN:

EXP: mm/yyyy

For Animal Treatment Only

Marketing Authorisation Holder:

Norbrook Laboratories Limited

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

4.02 ml pipette/blister

Flick

402 mg

Norbrook

EXP: mm/yyyy

BN: XXXX XXX

4.02 ml

40-60 kg



PACKAGE LEAFLET:

Flick 402 mg Spot-On Solution for Very Large Dogs Fipronil

This veterinary medicine is for the treatment of fleas and ticks in dogs weighing 40-60 kg bodyweight.

Please read all of this leaflet carefully before administering this product to your dog.

- Keep this leaflet you may need to read it again.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your veterinarian.

In this leaflet:

1. What Flick is

- 2. What Flick is used for
- 3. Before giving Flick to your dog
- 4. How to give this medicine to your dog
 - 5. Special Warnings
 - 6. Possible side effects
 - 7. Precautions you should take
 - 8. How to store Flick
 - 9. How to dispose of Flick
 - 10. Further information

1. What is Flick

Flick is a veterinary medicine containing the active ingredient Fipronil. Fipronil is an insecticide/acaricide in the phenylpyrazole family. It acts by inhibiting the GABA complex, binding to the chloride channel and thereby blocking pre- and post-synaptic transfer of chloride ions across the membrane. This results in uncontrolled activity of the central nervous system and death in insects and acarids.

2. What it is used for

Flick is for the treatment of infestations by fleas (*Ctenocephalides felis*). The product shows immediate effect against fleas and persistent activity against new infestations for up to 8 weeks.

Persistent activity has been demonstrated for up to 2 weeks against the Sheep Tick (*Ixodes ricinus*), for up to 3 weeks against the Brown Dog Tick (*Rhipicephalus sanguineus*) and up to 4 weeks against the Cow Tick (*Dermacentor reticulatus*). If ticks are present at the time of treatment, it may take up to one week for all to be killed.

3. Before giving the medicine to your dog

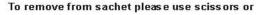
This product is suitable for most dogs, but should not be used on some. If you are in any doubt please contact our customer services department or your own veterinarian BEFORE using the product.

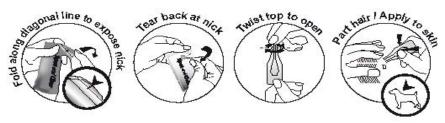
Do not use this product on

- Dogs weighing less than 40 kg.
- Puppies less than 8 weeks old.
- Sick or recovering animals.
- Rabbits the active ingredient is known to be toxic to rabbits, and may even kill them.
- Cats this product contains more active ingredient than is recommended for use on cats.
- Animals known to have previously had a reaction to one of the ingredients.
- Puppies or dogs that have already been treated with another flea control product.
- Puppies or dogs that have been administered Flick within the last 4 weeks.

4. How to give this medicine to your dog

- For external use only.
- Do not remove the pipette from the <u>sachet</u> until required for use, dispose of used pipettes immediately.
- Animals should be weighed accurately prior to treatment to ensure the correct product is being used.
- Do not apply the product on wounds or damaged skin.
- Avoid contact with the animals eyes. In case of accidental eye contact immediately and thoroughly flush the eyes with water
- Apply **one** pipette of product directly to the skin.
- For dogs over 60 kg use two pipettes of 2.68 ml.





How to apply product

- Hold the pipette upright.
- Tap the narrow part of the pipette to ensure the contents are within the main body of the pipette.
- Break back the snap-off top from the pipette along the scored line.
- Part the coat between the shoulder blades until the skin is visible.
- Place the tip of the pipette on the skin and squeeze gently at one or two spots to empty its contents onto the skin.

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 treated animals do not lick each other following treatment.

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 disappear within 48 hours post application.

For the optimal control of fleas and ticks the treatment schedule can be based on the local epidemiological situation.

In the absence of safety studies, do not re-apply the product for minimum of 4 weeks after treatment.

5. Special Warnings

The product does not prevent ticks from attaching to the animals, but ticks may be killed in the first 24-48 hours after attachment prior to full engorgement and therefore minimising the risk of transmission of diseases. Once dead, ticks will often drop off the animal, but any remaining ticks may easily be removed by a gentle pull.

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

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.

Avoid frequent swimming or shampooing of the animal as this may reduce the effectiveness of this product.

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

If your dog is pregnant or feeding, please consult your veterinarian before use.

Dogs should not be allowed to swim in watercourses for 2 days after application.

6. Possible side-effects for your dog

Like all medicines, side effects to Flick can occur although these are rare and usually mild.

- If licking of the application site occurs, a brief period of excessive salivation may be observed. This should go away without the need for veterinary treatment.
- Skin reactions, such as reddening, hair loss and itching may occur.
- Very rarely, neurological symptoms, such as depression or nervous signs, vomiting or respiratory signs have been reported after use.

If symptoms persist or worsen, or if you notice other effects not mentioned in this leaflet consult your veterinary surgeon, taking this leaflet with you.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions 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).

7. Precautions you should take yourself

- Treated animals should not be handled or played with until the application site has dried. Therefore evening application is recommended. Treated dogs should not be allowed to sleep with owners, especially children.
- This product can cause mucous membrane and eye irritation. Do not get the
 product on your skin or in your eyes or mouth. If skin contact does occur wash
 it off quickly with soap and water. In the case of accidental eye contact,
 immediately and thoroughly flush the eyes with clean water. If eye irritation
 continues seek medical advice and show the package leaflet to the doctor.
- Do not eat, drink or smoke while using this product.
- Wash hands thoroughly after use.
- People with a known hypersensitivity (allergy) to fipronil or any of the other ingredients should avoid contact with the product.
- For animal treatment only.
- Keep out of the sight and reach of children.

8. How to store this medicine

- This medicinal product does not require any special temperature storage conditions.
- Store in the original container in order to protect from light and moisture.
- This product is flammable. Keep away from heat, sparks, open flame or other sources of ignition.
- Do not use after the expiry date printed on the pack.
- The alcohol carrier may have adverse effect on painted, varnished or other household surfaces or furnishings.

9. How to dispose of this medicine

- Dispose of all waste material and containers in the household refuse.
- As the active ingredient is highly toxic to aquatic organisms, great care is needed to ensure that the product does not reach drains, ponds, waterways or ditches.

10. Further Information

What is in this medicine?

The active ingredient is Fipronil (402 mg per pipette)

Other ingredients are: Butylhydroxyanisole (E320) and Butylhydroxyanisole (E321).

What does this medicine look like?

Flick is a clear, colourless to pale yellow solution.

Packaging Information:

This 4.02 ml pipette is moulded from a film composed of 3 layers: a polypropylene/COC/polypropylene, solvent free lacquer laminate and a copolymer of

polyethylene/EVOH/polyethylene. The pipettes are sealed within a child resistant 4-ply foil sachet composed of LDPE/nylon/aluminium foil/polyester film and presented in an outer box.

Flick is available in cartons of 1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90, 120 or 150 pipettes.

Not all pack sizes may be marketed.

Marketing authorisation holder

(EU)

Norbrook Laboratories (Ireland) Ltd. Rossmore Industrial Estate Monaghan Ireland

(UK)

Norbrook Laboratories Ltd Station Works Newry Co. Down BT35 6JP

Manufacturer responsible for batch release

Norbrook Laboratories Limited,

Station Works,

Newry,

Co. Down,

BT35 6JP,

United Kingdom

Norbrook Manufacturing Ltd. Rossmore Industrial Estate Monaghan Ireland

Distributor:

Lintbells Limited, West Barn, Fairclough Hall Farm, Halls Green, Weston, Hitchin,, Hertfordshire, SG4 7DP

ManA 2000

Vm 02000/4323

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For further information, call customer services on +44 (0)28 3026 4435 or e-mail customer.services@norbrook.co.uk

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