

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 0.5 ml pipettes

Johnsons Fipronil 50mg Spot-On Solution for Cats
Fipronil

Ticks and Fleas

For cats weighing more than 1 kg.

What is in this medicine?

Each pipette of product contains 50 mg of the active ingredient Fipronil.

Other ingredients are Butylhydroxyanisole (E320) [0.1 mg per pipette] and Butylhydroxytoluene (E321) [0.05 mg per pipette].

What is this medicine used for?

Johnsons Fipronil 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 5 weeks. The product shows acaricidal efficacy with killing effect against ticks (*Ixodes ricinus*) within 48 hours.

How do I use this medicine?

Read the package leaflet before use.

For External Use Only.

Do not remove the pipette from the sachet until use.

How should this medicine be stored?

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 cats 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, Newry, Co. Down, BT35 6JP, United Kingdom.

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Distributed by:

Johnson's Veterinary Products Ltd., Sutton Coldfield, West Midlands B75 7DF, UK

Tel: +44(0)121 1684

info@johnsons-vet.com

Vm 02000/4329

AVM-GSL - Authorised veterinary medicine – general sales list

EXP: mm/yyyy

BN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Sachet for 0.5 ml pipette/blister

Johnsons Fipronil 50mg Spot-On Solution for Cats
Fipronil

One pipette contains 50 mg of the active ingredient Fipronil.

For application directly to the skin.

0.5 ml

BN:

EXP: mm/yyyy

For Animal Treatment Only

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**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS**

0.5 ml pipette/blister

Johnsons Fipronil

50 mg

Norbrook

EXP: mm/yyyy

BN: XXXX XXX

0.5 ml



PACKAGE LEAFLET:

Johnsons Fipronil 50mg Spot-On Solution for Cats Fipronil

This veterinary medicine is for the treatment of fleas in cats weighing more than 1 kg bodyweight.

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

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

1. What is Spot and Clear

Johnsons Fipronil 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

Johnsons Fipronil 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 5 weeks. The product shows acaricidal efficacy with killing effect against ticks (*Ixodes ricinus*) within 48 hours.

3. Before giving the medicine to your cat

This product is suitable for most cats, 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.....

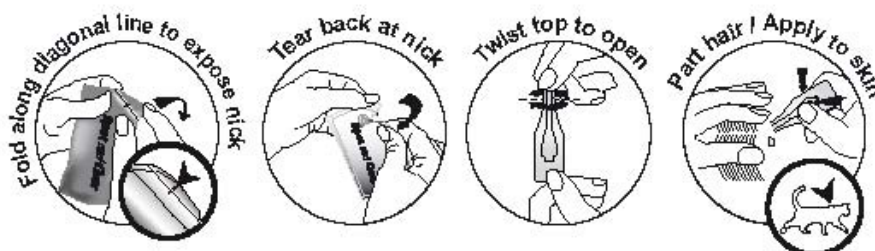
- Kittens or cats weighing less than 1 kg.
- Kittens less than 8 weeks old.
- Sick or recovering animals.
- Rabbits – the active ingredient is known to be toxic to rabbits, and may even kill them.
- Animals known to have previously had a reaction to one of the ingredients.

- Kittens or cats that have already been treated with another flea control product.
- Kittens or cats that have been administered Johnsons Fipronil within the last 4 weeks.

4. How to give this medicine to your cat

- For external use only.
- Do not remove the pipette from the sachet until required for use.
- 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.

To remove from sachet please use scissors or



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 24 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 a minimum of 4 weeks after treatment.

5. Special Warnings

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 start to 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 easily 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.

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

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

6. Possible side-effects for your cat

Like all medicines, side effects to Johnsons Fipronil 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.

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 cats 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.
- **Keep pipettes in original packaging and dispose of used pipettes immediately.**

10. Further Information

What is in this medicine?

The active ingredient is Fipronil (50 mg per pipette)

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

What does this medicine look like?

Johnsons Fipronil is a clear, colourless to pale yellow solution.

Packaging Information:

This 0.5 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.

Johnsons Fipronil 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
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BT35 6JP

Manufacturer responsible for batch release

Norbrook Laboratories Limited,
Station Works,
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Norbrook Manufacturing Ltd.
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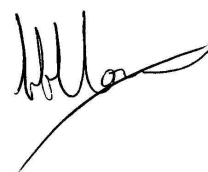
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For further information, call customer services on +44 (0)28 3026 4435 or e-mail
customer.services@norbrook.co.uk

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