

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fipnil 50 mg Spot-on solution for cats (FR,HU,IE)

Lifronil 50 mg Spot-on solution for cats (ES)

Fiprokill 50mg Spot-on solution for cats (RO)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One 0.5 ml pipette contains:

Active substance:

Fipronil 50 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Butylhydroxyanisole E320	0.1 mg
Butylhydroxytoluene E321	0.05 mg
Benzyl alcohol E1519	
Diethylene glycol monoethyl ether	

Clear, pale amber solution.

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each target species

Treatment of flea (*Ctenocephalides* spp.) infestations.

The veterinary medicinal product has a persistent insecticidal efficacy for up to 5 weeks against fleas (*Ctenocephalides* spp.).

The veterinary medicinal product has not demonstrated an immediate acaricidal effect against ticks but has demonstrated persistent acaricidal efficacy for up to 2 weeks against *Ixodes ricinus* and 1 week against *Dermacentor reticulatus* and *Rhipicephalus sanguineus*. If ticks of these species are present when the product is applied, all the ticks may not be killed within the first 48 hours but they may be killed within a week.

The veterinary medicinal product can be used as part of a treatment strategy for Flea Allergic Dermatitis, where this has been previously diagnosed by a veterinary surgeon.

3.3 Contraindications

In the absence of available data, the veterinary medicinal product should not be used on kittens less than 2 months old and/or weighing less than 1 kg.

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

Do not use in rabbits, as adverse drug reactions and even death could occur.
Do not use in cases of hypersensitivity to the active substance or to any of excipients.

3.4 Special warnings

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.

The veterinary medicinal 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.

Avoid frequent swimming/bathing or shampooing the animal because the maintenance of effectiveness of the veterinary medicinal product in these cases has not been tested.

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

When used as part of a strategy for the treatment of Flea Allergy Dermatitis, monthly applications to the allergic patient and to other cats and dogs in the household are recommended.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Animals should be weighed accurately prior to treatment to ensure that the correct size of pipette is applied.

Avoid contact with the animal's eyes. In the case of accidental eye contact, immediately and thoroughly flush the eyes with water.

Do not apply the veterinary medicinal product on wounds or damaged skin.

It is important to make sure that the veterinary medicinal 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

This veterinary medicinal product can cause mucous membrane and eye irritation. Therefore, contact between the veterinary medicinal 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 skin. If this occurs, wash hands with soap and water. Wash hands after use.

Animals or operators with a known hypersensitivity to fipronil or excipients should avoid contact with the veterinary medicinal product.

Treated animals should not be handled until the application site is dry, and children should be kept away from 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 the protection of the environment:

Not applicable.

Other precautions:

The veterinary medicinal product may have adverse effects on painted, varnished or other household surfaces or furnishings.

This veterinary medicinal product is flammable. Keep away from heat, sparks, open flame or other sources of ignition.

3.6 Adverse events

Cat:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Hypersalivation ¹ Application site reactions ² (Skin Discolouration, Skin Squamosis, Alopecia, Pruritus, Erythema) Generalised itching General hair loss Neurological disorders ³ (Hyperaesthesia, Central nervous system depression, Neurological symptoms) Vomiting
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¹ If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.

² Transient cutaneous reactions.

³ Reversible symptoms.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

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 queens. Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Spot-on use.

Route of administration and dosage:

External use only.

Administer by topical application to the skin 1 pipette of 0.5 ml per animal.

Method of administration:

Remove the pipette from the sachet. Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents are within the main body of the pipette. Snap back the tip. Part the cat's coat until the skin is visible. Place the tip of the pipette directly against the bared skin and squeeze gently to empty its contents at two points along the cat's back, preferably at the base of the head and 2-3 cm further back, emptying approximately half the volume at each site. Squeeze the pipette several times to ensure dosing is complete.

It is important to make sure that the veterinary medicinal 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.

Care should be taken to avoid excessive wetting of the hair with the veterinary medicinal 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. Scaling and crystalline deposits on the hairs may also be observed at the site of application for up to 48 hours.

Treatment schedule:

For optimal control of flea and/or tick infestation the treatment schedule can be based on the local epidemiological situation.

In the absence of safety studies, the minimum treatment interval is 4 weeks.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse effects were observed in target animal safety studies in cats and kittens aged 2 months and older and weighing about 1 kg treated at five times the recommended dose over 3 consecutive months. The risk of adverse effects may increase in cases of overdose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QP53AX15

4.2 Pharmacodynamics

Fipronil is an insecticide and acaricide belonging to 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 cell membranes. This results in uncontrolled activity of the central nervous system and death of insects or acarids.

Fipronil exhibits insecticidal activity against fleas (*Ctenocephalides* spp.) and acaricidal activity against ticks in the cat.

Fleas will be killed within 48 hours. Ticks will usually be killed within 48 hours after contact with fipronil, however if *Ixodes ricinus*, *Dermacentor reticulatus* or *Rhipicephalus sanguineus* ticks are present when the veterinary medicinal product is applied, all the ticks may not be killed within the first 48 hours.

4.3 Pharmacokinetics

Absorption:

Absorption of fipronil through the skin is negligible.

Distribution:

After topical application, the veterinary medicinal product will spread from the site of treatment to cover the entire surface of the animal within 24-48 hours.

Biotransformation:

Fipronil is mainly metabolised to its sulfone derivative, which also possesses insecticidal and acaricidal properties.

Elimination:

The concentrations of fipronil on the hair decrease with time.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

A 0.5 ml white pipette composed of a heat-formed shell of a polypropylene/cyclic olefin copolymer/polypropylene layer and a polyethylene/ethylene vinyl alcohol/polyethylene layer.

A Cardboard box with 1, 2, 3, 4, 6, 8, 9, 10, 12, 15, 18, 20, 21, 24, 30, 60, 90 or 150 pipettes in individual foil sachets.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as fipronil may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

<{MM/YYYY}>

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

IE: Veterinary medicinal product subject to veterinary prescription.

FR, HU, RO, ES: Veterinary medicinal product not subject to veterinary prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<https://medicines.health.europa.eu/veterinary>).

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fipnil 50 mg Spot-on solution for cats (FR,HU,IE)

Lifronil 50 mg Spot-on solution for cats (ES)

Fiprokill 50mg Spot-on solution for cats (RO)

2. STATEMENT OF ACTIVE SUBSTANCES

One pipette contains:

Fipronil: 50 mg

3. PACKAGE SIZE

1 x 0.5 ml

2 x 0.5 ml

3 x 0.5 ml

4 x 0.5 ml

6 x 0.5 ml

8 x 0.5 ml

9 x 0.5 ml

10 x 0.5 ml

12 x 0.5 ml

15 x 0.5 ml

18 x 0.5 ml

20 x 0.5 ml

21 x 0.5 ml

24 x 0.5 ml

30 x 0.5 ml

60 x 0.5 ml

90 x 0.5 ml

150 x 0.5 ml

4. TARGET SPECIES

Cats.

5. INDICATIONS

For products not subject to veterinary prescription

Treatment of fleas (*Ctenocephalides* spp.). Protects against fleas for 5 weeks. Protects against ticks (*Ixodes ricinus*) for 2 weeks and ticks (*Dermacentor reticulatus* and *Rhipicephalus sanguineus*) for 1 week. Aids in the control of Flea Allergic Dermatitis.

6. ROUTES OF ADMINISTRATION

Spot-on use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{pipette}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fipnil 50 mg (FR, HU, IE)

Lifronil 50 mg (ES)

Fiprokill 50 mg (RO)

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

0.5 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Sachet}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fipnil 50 mg (FR, HU, IE)

Lifronil 50 mg (ES)

Fiprokill 50 mg (RO)

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Fipronil 50 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Fipnil 50 mg Spot-on solution for cats (FR, HU, IE)
Lifronil 50 mg Spot-on solution for cats (ES)
Fiprokill 50mg Spot-on solution for cats (RO)

2. Composition

One 0.5 ml pipette contains:

Active substance:

Fipronil 50 mg

Excipients:

Butylhydroxyanisole E320	0.1 mg
Butylhydroxytoluene E321	0.05 mg

Clear, pale amber solution.

3. Target species

Cats 

4. Indications for use

Treatment of flea (*Ctenocephalides* spp.) infestations.

The veterinary medicinal product has a persistent insecticidal efficacy for up to 5 weeks against fleas (*Ctenocephalides* spp.).

The veterinary medicinal product has a persistent efficacy for up to 2 weeks against ticks (*Ixodes ricinus*) and 1 week against ticks (*Dermacentor reticulatus* and *Rhipicephalus sanguineus*). If ticks of these species are present when the veterinary medicinal product is applied, all the ticks may not be killed within the first 48 hours but they may be killed within a week.

The veterinary medicinal product can be used as part of a treatment strategy for Flea Allergic Dermatitis, where this has been previously diagnosed by a veterinary surgeon.

5. Contraindications

Do not use on kittens less than 8 weeks old or cats or kittens weighing less than 1 kg.

Do not use on sick (e.g. diseases affecting the whole body, fever...) or animals recovering after an illness.

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

Do not use in cases of hypersensitivity to the active substance or to any of excipients.

6. Special warnings

Special warnings:

The veterinary medicinal 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. Usually at this point ticks will not have taken blood from the animal. This minimises but does not exclude the chance of disease transmission to the animal. 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 the best control of flea infestation in multi-pet household, all dogs and cats in the household should be treated with a suitable insecticide product.

When used as part of a strategy for the treatment of Flea Allergy Dermatitis, monthly applications to the allergic patient and to other cats and dogs in the household are recommended.

Special precautions for safe use in the target species:

Animals should be weighed accurately prior to treatment to ensure that the correct size of pipette is applied.

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 veterinary medicinal 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 veterinary medicinal product on wounds or damaged skin.

Use in pregnancy and feeding queens only on advice from your veterinarian.

There are no known incompatibilities.

The risk of adverse effects may increase in cases of severe overdose.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Contact between the veterinary medicinal product and the mouth or eyes should be avoided as this product can cause irritation to these areas.

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.

Avoid contents coming into contact with the skin. If this occurs, wash hands with soap and water.

Wash hands after use.

Animals or pet owners with a known hypersensitivity to fipronil or the other ingredients should avoid contact with the veterinary medicinal product.

Treated animals should not be handled until the application site is dry, and children should be kept away from 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.

If the veterinary medicinal product is accidentally eaten or swallowed, contact your doctor immediately and show them the package leaflet.

Do not smoke, drink or eat during application.

For animal treatment only.

Other precautions:

This veterinary medicinal product is flammable. Keep away from heat, sparks, open flame or other sources of ignition.

The veterinary medicinal product may affect painted, varnished or other household surfaces or furnishings.

7. Adverse events

Cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersalivation ¹ Application site reactions (Skin Discolouration, Skin Squamosis (Scaly skin), Alopecia (Hair loss), Pruritus (Itching), Erythema (Redness)) ² Generalised itching General hair loss Neurological disorders (Hyperaesthesia (Increased sensitivity to stimuli), Central nervous system depression, Neurological symptoms) ³ Vomiting
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¹ If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the ingredients.

² Transient cutaneous reactions.

³ Reversible symptoms.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or its local representative> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Spot-on use.

Route of administration and dosage:

External use only.

Administer by topical application to the skin as follows:

1 pipette of 0.5 ml per cat.

Method of administration:

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

Part the cat's coat until the skin is visible. Place the tip of the pipette directly against the bared skin and squeeze gently to empty its contents at two points along the cat's back, preferably at the base of the head and 2-3 cm back, emptying approximately half the volume at each site. Squeeze the pipette several times to ensure dosing is complete.

Care should be taken to avoid excessive wetting of the hair with the veterinary medicinal 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. Scaling and crystalline deposits on the hairs may also be seen at the site of application for up to 48 hours.

Treatment schedule:

For optimal control of flea and/or tick infestation the treatment schedule can be based on the local epidemiological situation.

In the absence of safety studies, the minimum treatment interval is 4 weeks.

9. Advice on correct administration

Discard any opened pipettes.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and pipette after "Exp". The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

This veterinary medicinal product should not enter water courses as fipronil may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived therefrom in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

IE: Veterinary medicinal product subject to veterinary prescription.

FR, HU, RO, ES: Veterinary medicinal product not subject to veterinary prescription.

14. Marketing authorisation numbers and pack sizes

1, 2, 3, 4, 6, 8, 9, 10, 12, 15, 18, 20, 21, 24, 30, 60, 90 or 150 pipettes.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<https://medicines.health.europa.eu/veterinary>).

16. Contact details

Marketing authorisation holder <,> <and> <manufacturer responsible for batch release> <and contact details to report suspected adverse events>:

Chanelle Pharmaceuticals Manufacturing Ltd.,

Loughrea,

Co. Galway.

Ireland.

Telephone: +353 (0)91 841788

vetpharmacoviggroup@chanellegroup.ie

<Local representatives <and contact details to report suspected adverse events>:>

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

<17. Other information>