

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norbrook Fipronil 50 mg Spot-On Solution for cats

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One 0.5 ml pipette contains:

### Active substances:

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
Povidone K12	
Polysorbate 80	
Butyl Alcohol	
Diethylene Glycol Monoethyl Ether	

A clear, colourless to pale yellow solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cats.

### 3.2 Indications for use for each target species

For the treatment of infestations by fleas (*Ctenocephalides felis*). The veterinary medicinal product shows immediate insecticidal effect and persistent insecticidal activity against new infestations by adult fleas for up to 5 weeks.

The veterinary medicinal product shows acaricidal efficacy with killing effect against ticks (*Ixodes ricinus*) within 48 hours.

### 3.3 Contraindications

In the absence of available data, the veterinary medicinal product should not be used on kittens less than 8 weeks 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 known hypersensitivity to the active substance or to any of the excipients.

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

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

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.

### **3.5 Special precautions for use**

#### Special precautions for safe use in the target species:

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.

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

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

#### 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 of the veterinary medicinal product with mouth and eyes should be avoided.

In case of accidental eye contact, immediately and thoroughly rinse eyes with plain water. If irritation to the eyes persists, seek medical advice immediately and show the package leaflet or the label to the physician.

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

Wash hands after use.

Do not smoke, drink or eat during application.

People with a known hypersensitivity to fipronil or any of the excipients should avoid contact with the veterinary medicinal product.

Treated animals should not be handled until this 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.

Keep pipettes in original packaging and dispose of used pipettes immediately.

#### Special precautions for the protection of the environment:

Not applicable.

### Other precautions:

The alcohol carrier 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**

Target species: Cats.

Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	Application site reactions (Skin scaling <sup>1</sup> , Hair loss <sup>1</sup> , Itching <sup>1</sup> , Reddening <sup>1</sup> ). Generalised Itching, Hair loss. Hypersalivation <sup>2</sup> , Vomiting. Neurological disorders <sup>3</sup> (Hyperaesthesia, Central nervous system depression, Neurological symptoms) <sup>3</sup>
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<sup>1</sup> Transient.

<sup>2</sup> If licking occurs, a brief period of excessive salivation may be observed due mainly to the nature of the carrier.

<sup>3</sup> Reversible.

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 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 veterinary medicinal product in pregnant and lactating animals. 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.

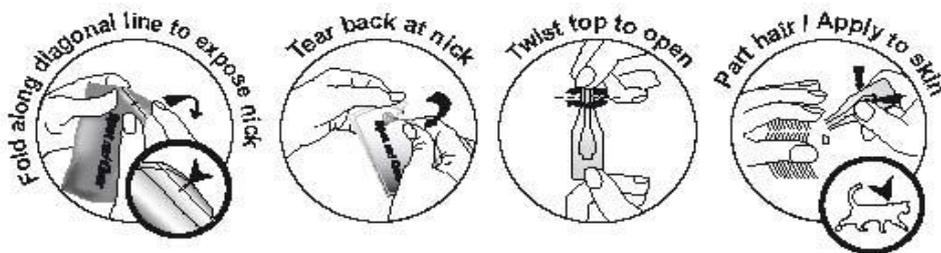
For external use only.

Animals should be weighed accurately prior to treatment.

Dosage: 1 pipette of 0.5 ml per cat (approximately 7.5 – 15 mg/kg).

Method of Administration: Hold 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 spot-on pipette along the scored line.

To remove from sachet please use scissors or



Part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze gently to empty its contents onto the skin, preferably at two spots, one at the base of the skull and a second 2-3 cm further back.

It is important to ensure 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.

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)**

The toxicity of the veterinary medicinal product administered to the skin is very low. The risk of experiencing adverse effects may however increase when overdosing, so animals should always be treated with the correct pipette size according to bodyweight.

### **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 IMMUNOLOGICAL INFORMATION**

### **4.1 ATCvet code : QP53AX15**

### **4.2 Pharmacodynamics**

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.

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

Newly arriving fleas are killed within 24 hours of landing on the animal.

The veterinary medicinal product is effective against flea infestation for approximately 5 weeks and shows killing effect against ticks (*Ixodes ricinus*) within 48 hours, depending on the level of challenge.

### **4.3 Pharmacokinetics**

Fipronil is mainly metabolised to its sulfone derivative (RM1602), which also possesses insecticidal and acaricidal properties.

After a local application of fipronil to the cat, systemic absorption is negligible.

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: 3 years.

### **5.3 Special precautions for storage**

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

### **5.4 Nature and composition of immediate packaging**

0.5 ml pipette, 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.

Boxes of 1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90, 120 or 150 pipettes.

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**

Norbrook Laboratories (Ireland) Limited

**7. MARKETING AUTHORISATION NUMBER(S)**

**8. DATE OF FIRST AUTHORISATION**

Date of first authorisation: 6th July 2012

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

{MM/YYYY}

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product not subject to prescription [AT, BG, EE, ES, HU, IT, LV, LT, NL, RO].

Veterinary medicinal product subject to prescription [IE, UK-NI]

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 of 1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90, 120 or 150, 0.5 ml pipettes**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Norbrook Fipronil 50 mg Spot-On Solution for Cats

**2. STATEMENT OF ACTIVE SUBSTANCES**

One 0.5 ml pipette contains:

**Active Substance:**

Fipronil 50 mg

**Excipients:**

Butylhydroxyanisole E320 0.1 mg

Butylhydroxytoluene E321 0.05 mg

**3. PACKAGE SIZE**

1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90, 120 or 150, 0.5 ml pipettes

**4. TARGET SPECIES**

Cats

**5. INDICATIONS**

*For products not subject to veterinary prescription*

Ticks and Fleas.

For the treatment of infestations by fleas (*Ctenocephalides felis*). The veterinary medicinal product shows immediate insecticidal effect and persistent insecticidal activity against new infestations by adult fleas for up to 5 weeks.

The veterinary medicinal product shows acaricidal efficacy with killing effect against ticks (*Ixodes ricinus*) within 48 hours.

**6. ROUTES OF ADMINISTRATION**

Spot-on use.

For cats weighing more than 1 kg.

Do not remove the pipette from the sachet until required for use.

For external use only.

**7. WITHDRAWAL PERIODS**

Not applicable.

**8. EXPIRY DATE**

Exp. {mm/yyyy}

**9. SPECIAL STORAGE PRECAUTIONS**

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

**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**

Norbrook Laboratories (Ireland) Limited

**14. MARKETING AUTHORISATION NUMBERS**

EU/0/00/000/000

**15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

Sachet for 0.5 ml pipette/blister

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Norbrook Fipronil 50 mg Spot-On Solution

**2. STATEMENT OF ACTIVE SUBSTANCES**

One 0.5 ml pipette contains:

**Active Substance:**

Fipronil 50mg

**3. TARGET SPECIES**

Cats

**4. ROUTES OF ADMINISTRATION**

Spot-on use.

By topical application to the skin.

**5. WITHDRAWAL PERIODS**

Not applicable

**6. EXPIRY DATE**

Exp. {mm/yyyy}

**7. SPECIAL STORAGE PRECAUTIONS**

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

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

Norbrook Laboratories (Ireland) Limited

**9. BATCH NUMBER**

Lot {number}

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

**0.5 ml pipette/blister**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Norbrook Fipronil



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

One 0.5 ml pipette contains:

**Active substance:**

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

Norbrook Fipronil 50 mg Spot-On Solution for cats

### 2. Composition

One 0.5 ml pipette contains:

#### Active substance:

Fipronil 50 mg

#### Excipients:

Butylhydroxyanisole E320 0.1 mg

Butylhydroxytoluene E321 0.05 mg

A clear, colourless to pale yellow solution.

### 3. Target species

Cats.



### 4. Indications for use

For the treatment of infestations by fleas (*Ctenocephalides felis*). The veterinary medicinal product shows immediate insecticidal effect and persistent insecticidal activity against new infestations by adult fleas for up to 5 weeks.

The veterinary medicinal product shows acaricidal efficacy with killing effect against ticks (*Ixodes ricinus*) within 48 hours.

### 5. Contraindications

In the absence of available data, the veterinary medicinal product should not be used on kittens less than 8 weeks 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 known hypersensitivity to the active substance or to any of the 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 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 optimum control of flea problems in a multi-pet household, all dogs and cats in the household should be treated with a suitable insecticide.

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

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.

Special precautions for safe use in the target species:

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

For external use only.

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.

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

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

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 of the veterinary medicinal product with mouth and eyes should be avoided.

In case of accidental eye contact, immediately and thoroughly rinse eyes with plain water. If irritation to the eyes persists seek medical advice immediately and show the package leaflet or the label to the physician.

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

Wash hands after use.

Do not smoke, drink or eat during application.

People with a known hypersensitivity to fipronil or any of the other ingredients should avoid contact with the veterinary medicinal product.

Treated animals should not be handled until this 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.

Keep pipettes in original packaging and dispose of used pipettes immediately.

Other precautions:

The alcohol carrier 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.

Overdose:

The toxicity of the veterinary medicinal product administered to the skin is very low. The risk of experiencing adverse effects may however increase when overdosing, so animals should always be treated with the correct pipette size according to bodyweight.

#### 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 veterinary medicinal product in pregnant and lactating animals. Use only according to the benefit-risk assessment by the responsible veterinarian.

### **7. Adverse events**

Cats:

Very rare ( $< 1$ animal / 10,000 animals treated, including isolated reports):	Application site reactions (Skin scaling <sup>1</sup> , Hair loss <sup>1</sup> , Itching <sup>1</sup> , Reddening <sup>1</sup> ). Generalised Itching, Hair loss. Hypersalivation <sup>2</sup> , Vomiting. Neurological disorders <sup>3</sup> (Hyperaesthesia, Central nervous system depression, Neurological symptoms)
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<sup>1</sup> Transient.

<sup>2</sup> If licking occurs, a brief period of excessive salivation may be observed due mainly to the nature of the carrier.

<sup>3</sup> Reversible.

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 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.

For external use only.

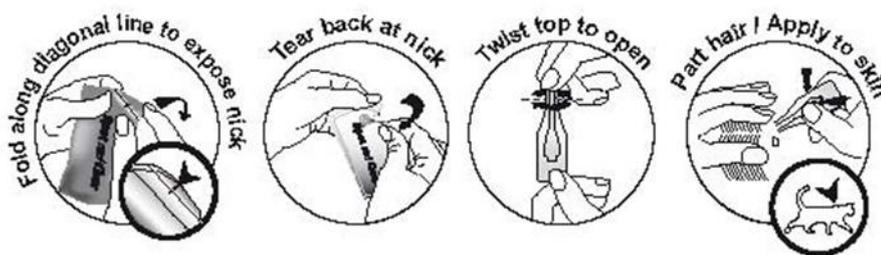
Do not remove the pipette from the sachet until required for use.

Dosage: 1 pipette of 0.5 ml per cat (approximately 7.5 – 15 mg/kg).

Method of Administration: Hold 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 spot-on 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 to empty its contents onto the skin, preferably at two spots, one at the base of the skull and a second 2-3 cm further back.

To remove from sachet please use scissors or



## 9. Advice on correct administration

It is important to ensure 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.

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.

Animals should be weighed accurately prior to treatment.

## 10. Withdrawal periods

Not applicable.

## 11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special temperature storage conditions.

Store in the original container in order to protect from light and moisture.

Do not use this veterinary medicinal product after the expiry date stated on the label 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 thereof 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

Veterinary medicinal product not subject to prescription [AT, BG, EE, ES, HU, IT, LV, LT, NL, RO].

Veterinary medicinal product subject to prescription [IE, UK-NI]

#### **14. Marketing authorisation numbers and pack sizes**

0.5 ml pipette, 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.

Boxes of 1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90, 120 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 contact details to report suspected adverse events>:

Norbrook Laboratories (Ireland) Limited  
Rossmore Industrial Estate  
Monaghan  
Ireland  
Tel : +44 (0)28 3026 4435  
Email: phvdept@norbrook.co.uk

Manufacturer responsible for batch release:

Norbrook Laboratories Limited  
Station Works, Camlough Road  
Newry, Co. Down, BT35 6JP  
Northern Ireland

Norbrook Manufacturing Limited  
Rossmore Industrial Estate  
Monaghan  
Ireland

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**

### **Mode of Action**

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.