

**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dixie 50 mg Spot-On solution for cats

France: Dixie Fipronil 50 mg Solution pour Spot-On pour Chats

Portugal: Dixie Fipronil 50 mg solução para unção punctiforme para gatos

Spain: Dixie Fipronilo 50 mg Solución Spot-On para gatos

UK(NI): Diptron 50 mg Spot-on Solution for cats

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pipette (0.5 ml) 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)	0.10 mg
Butylhydroxytoluene (E321)	0.05 mg
Povidone K25	-
Polysorbate 80	-
Ethanol 96%	-
Diethylene glycol monoethyl ether	-

Clear, colourless to yellow solution

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cat

### 3.2 Indications for use for each target species

'Treatment and prevention of flea infestations (*Ctenocephalides felis*). Fleas present on the animal at the time of product application will be killed within 48 hours. The product has persistent insecticidal efficacy lasting for 4 weeks against *Ctenocephalides felis* fleas.

Treatment and prevention of tick infestations (*Rhipicephalus turanicus*). Ticks present on the animal at the time of product application will be killed within 48 hours. The product has persistent acaricidal efficacy for 4 weeks against *Rhipicephalus turanicus* ticks.'

### 3.3 Contraindications

Do not use on kittens less than 9 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 reactions and even death could occur.

Do not apply on wounds or damaged skin.

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

### **3.4 Special warnings**

During the period of expected efficacy, ticks will be killed and fall off the host within 48 hours of infestation, usually without having had a blood meal. However, the attachment of single ticks may occur after treatment and therefore the transmission of infectious diseases by ticks cannot be excluded. Once dead, ticks will often drop off the animal, but any remaining ticks can be removed carefully.

The impact of bathing/immersion in water or shampooing on product effectiveness has not been investigated and therefore cannot be recommended, especially within 2 days of product application.

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.

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:

For external use only.

Avoid contact with the animal's eyes.

Animals should be weighed accurately prior to treatment.

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 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 may cause neurotoxicity. Keep stored pipettes in the original packaging until ready to use. In order to prevent children from getting access to used pipettes, dispose of used pipettes immediately.

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

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 case of accidental ocular exposure or irritation of the eyes during administration, these should be rinsed immediately and thoroughly with plain water. If eye irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.

Avoid contents coming into contact with the fingers. In case of dermal exposure, wash immediately with soap and water.

Wash hands after use.

Do not smoke, drink or eat during application.

Treated animals should not be handled until the application site is dry, and children should not be allowed to play with them 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:

Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

### **3.6 Adverse events**

Cat:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersalivation <sup>1</sup> / drooling <sup>1</sup>
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	<p>Application site disorders<sup>2</sup> (skin discolouration, local alopecia, pruritus, erythema)</p> <p>Pruritus<sup>3</sup>, alopecia</p> <p>Excessive salivation, Vomiting</p> <p>Neurological disorders<sup>4</sup>(hyperesthesia, depression, neurological signs),</p> <p>Respiratory signs.</p>

<sup>1</sup>If licking occurs, a brief period of hypersalivation/drooling may be observed due mainly to the nature of the carrier.

<sup>2</sup>Transient cutaneous reactions

<sup>3</sup>General

<sup>4</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 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 in rats have not produced any evidence of teratogenic or fetotoxic effects. The safety of the veterinary medicinal product has not been established during pregnancy and lactation. 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.

1 pipette of 0.5 mL per cat

#### **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 at one or two spots to empty its contents onto the skin.

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.

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 of 9 weeks of age and weighing about 1 kg where the animals received the recommended dose, three (3X) and five (5X) times the recommended dose. The risk of experiencing adverse effects may however increase with overdosing (see section 3.6.). Itching may occur following treatment.

### **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/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 an insecticidal and acaricidal activity against fleas (*Ctenocephalides spp.*), ticks (*Rhipicephalus spp.*) in the cat.

### **4.3 Pharmacokinetics**

#### **\*Absorption**

After local application of the product in the cat, absorption of fipronil through the skin is negligible.

#### **\*Distribution**

After topical application, the product will spread from the site of treatment to cover the entire surface of the animal. A concentration gradient of fipronil is set up on the fur of the animal extending from the point of application to the peripheral areas (lumbar zones, flanks, ...).

#### **\*Biotransformation**

Fipronil is mainly metabolised to its sulfone derivative (RM1602), 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**

Not applicable.

### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf-life after first opening the immediate packaging: immediate use.

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

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

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

White opaque plastic spot-on pipettes of COEX- High Density Polyethylene -Extrusion material. Each pipette is packaged in blisters composed by plastic supports (PVC-PE) to hold them and covered by a polyester / polyethylene complex.

##### Package sizes:

1, 2, 3, 4, 5, 6, 8, 10, 12, 24, 30, 60, 90, 120 or 150 pipettes in carton box  
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**

QUIMICA DE MUNGUÍA S.A. (QUIMUNSA)

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

#### **8. DATE OF FIRST AUTHORISATION**

Date of first authorisation:

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

#### **10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product not subject to 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 boxes with pipettes of 0.5 mL

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

Dixie 50 mg Spot-On solution

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each pipette of 0.5 ml contains:

Fipronil..... 50 mg

**3. PACKAGE SIZE**

1, 2, 3, 4, 5, 6, 8, 10, 12, 24, 30, 60, 90, 120 or 150 pipettes in carton box

**4. TARGET SPECIES**

Cat

**5. INDICATIONS**

Treatment and prevention of flea infestations (*Ctenocephalides felis*). Fleas present on the animal at the time of product application will be killed within 48 hours. The product has persistent insecticidal efficacy lasting for 4 weeks against *Ctenocephalides felis* fleas.

Treatment and prevention of tick infestations (*Rhipicephalus turanicus*). Ticks present on the animal at the time of product application will be killed within 48 hours. The product has persistent acaricidal efficacy for 4 weeks against *Rhipicephalus turanicus* ticks.

**6. ROUTES OF ADMINISTRATION**

Spot-on use.

1 pipette of 0.50 ml per cat.

**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 at one or two spots to empty its contents onto the skin.

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.

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

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. {mm/yyyy}

**9. SPECIAL STORAGE PRECAUTIONS****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****14. MARKETING AUTHORISATION NUMBERS****15. BATCH NUMBER**

Batch {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS****Pipettes of 0.5 mL****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Dixie 50 mg

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

Each pipette of 0.5 ml contains:

Fipronil 50 mg

**3. BATCH NUMBER**

Batch {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Dixie 50 mg Spot-On solution for cats

### 2. Composition

Each pipette of 0.5 ml contains:

#### Active substance:

Fipronil.....50 mg

#### Excipients:

Butylhydroxyanisole (E320).....0.10 mg  
Butylhydroxytoluene (E321)..... 0.05 mg

Clear, colourless to yellow solution.

### 3. Target species

Cat

### 4. Indications for use

Treatment and prevention of flea infestations (*Ctenocephalides felis*). Fleas present on the animal at the time of product application will be killed within 48 hours. The product has persistent insecticidal efficacy lasting for 4 weeks against *Ctenocephalides felis* fleas.

Treatment and prevention of tick infestations (*Rhipicephalus turanicus*). Ticks present on the animal at the time of product application will be killed within 48 hours. The product has persistent acaricidal efficacy for 4 weeks against *Rhipicephalus turanicus* ticks.'

### 5. Contraindications

Do not use on kittens less than 9 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 reactions and even death could occur.

Do not apply on wounds or damaged skin.

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

### 6. Special warnings

During the period of expected efficacy, ticks will be killed and fall off the host within 48 hours of infestation, usually without having had a blood meal. However, the attachment of single ticks may occur after treatment and therefore the transmission of infectious diseases by ticks cannot be excluded. Once dead, ticks will often drop off the animal, but any remaining ticks can be removed carefully.

The impact of bathing/immersion in water or shampooing on product effectiveness has not been investigated and therefore cannot be recommended, especially within 2 days of product application.

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.

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 use in the target species:

For external use only.

Avoid contact with the animal's eyes.

Animals should be weighed accurately prior to treatment.

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 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 may cause neurotoxicity. Keep stored pipettes in the original packaging until ready to use. In order to prevent children from getting access to used pipettes, dispose of used pipettes immediately.

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

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 case of accidental ocular exposure or irritation of the eyes during administration, these should be rinsed immediately and thoroughly with plain water. If eye irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.

Avoid contents coming into contact with the fingers. In case of dermal exposure, wash immediately with soap and water.

Wash hands after use.

Do not smoke, drink or eat during application.

Treated animals should not be handled until the application site is dry, and children should not be allowed to play with them 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:**

Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

**Pregnancy and lactation:**

Laboratory studies in rats have not produced any evidence of teratogenic or fetotoxic effects. The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit--risk assessment by the responsible veterinarian.

**Interaction with other medicinal products and other forms of interaction:**

None known.

**Overdose:**

No adverse effects were observed in target animal safety studies in cats and kittens of 9 weeks of age and weighing about 1 kg where the animals received the recommended dose, three (3X) and five (5X) times the recommended dose. The risk of experiencing adverse effects may however increase with overdosing (see section Adverse events). Itching may occur following treatment.

**Major incompatibilities:**

Not applicable

**7. Adverse events**

Cats:

Rare (1 to 10 animals / 10,000 animals treated):
Hypersalivation <sup>1</sup> / drooling <sup>1</sup>
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Application site disorders <sup>2</sup> (skin discolouration, local alopecia, pruritus, erythema)
Pruritus <sup>3</sup> , alopecia
Excessive salivation, Vomiting Neurological disorders <sup>4</sup> (hyperesthesia, depression, neurological signs)
Respiratory signs

<sup>1</sup>If licking occurs, a brief period of hypersalivation /drooling may be observed due mainly to the nature of the carrier.

<sup>2</sup>Transient cutaneous reactions

<sup>3</sup>General

<sup>4</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 <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: <{national system details} [*listed in Appendix I\**]>.

*[\*For the printed material, please refer to the guidance of the annotated QRD template.]*

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

Spot-on use.1 pipette of 0.5 mL per cat

### **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 at one or two spots to empty its contents onto the skin.

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.

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

## **9. Advice on correct administration**

None

## **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 storage conditions  
Shelf-life after first opening the immediate packaging: immediate use.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton 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.

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

### **Package sizes:**

1, 2, 3, 4, 5, 6, 8, 10, 12, 24, 30, 60, 90, 120 or 150 pipettes in carton box  
Not all pack sizes may be marketed

## **15. Date on which the package leaflet was last revised**

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

QUIMICA DE MUNGUÍA S.A.  
Derio Bidea, 51  
48100 Munguía- Vizcaya  
SPAIN  
Tel. +34 946 741 085  
[complaints@quimunsa.com](mailto:complaints@quimunsa.com)  
[info@quimunsa.com](mailto:info@quimunsa.com)

### Local representatives and contact details to report suspected adverse reactions:

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

**Ελλάδα**

Vasilios Nikas DVM (Anicell)  
Dimokratias Ave 257  
EL-13671  
Τηλ: 0030 211 411 0700  
0030 693 746 9226  
bill@anicell.gr

**España**

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**Polska**

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**Portugal**

Inês Dias (Propecuária-Veterinária e  
Farmacêutica)  
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Zona Industrial de Porto de Mós Portugal  
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direcao.tecnica@propecuaria.pt