

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE>**  
**Carton boxes**

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

DIXIE 50 mg Spot-On solution for Cats  
Fipronil

France: DIXIE Fipronil 50 mg Solution pour SPOT-ON pour Chats  
Fipronil

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

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

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each pipette of 0.5 ml contains:

**Active substance:**

Fipronil 50 mg

**Excipients:**

Butylhydroxyanisole (E320) 0.10 mg

Butylhydroxytoluene (E321) 0.05 mg

**3. PHARMACEUTICAL FORM**

Spot-on solution.

Clear colourless to yellow solution

**4. PACKAGE SIZE**

Package sizes:

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

**5. TARGET SPECIES**

Cats

**6. INDICATION(S)**

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.

## **7. METHOD AND ROUTE(S) 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.

## **8. WITHDRAWAL PERIOD**

Not applicable

## **9. SPECIAL WARNING(S), IF NECESSARY**

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 case of hypersensitivity to the active substance or to any of the excipients.

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 animals

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.

#### User warnings. Please read before ever use.

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

This product can cause mucous membrane and eye irritation. Therefore, contact of the product with mouth and 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, 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.

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.

<b>10. EXPIRY DATE</b>
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<EXP {month/year}>

**11. SPECIAL STORAGE CONDITIONS**

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

**12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY.**

Dispose of waste material in accordance with local requirements.

Disposal: read package leaflet.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only.

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

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Química de Munguía S.A.  
Derio Bidea, 51  
48100 Minguia (Vizcaya)  
Spain

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

EU/2/00/000/000

**17. MANUFACTURER'S BATCH NUMBER**

<Batch> {number}

**MINIMUM PARTICULARS TO APPEAR ON PIPETTES**

**Coex pipettes**

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Fipronilo

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

QUIMUNSA

**3. EXPIRY DATE**

Impressed: {month/year}

**4. BATCH NUMBER**

Impressed: {number}

**5. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.