PACKAGE LEAFLET

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**

Read this information carefully before each use for full instructions and warnings. Keep this leaflet in the outer package for future reference.

1. NAME AND ADDRESS OF THE MARKETING AUTHORIZATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR THE BATCH RELEASE, IF DIFFERENT

Marketing Authorization Holder and manufacturer responsible of batch release:

QUIMICA DE MUNGUÍA S.A.
Derio Bidea, 51
48100 Munguía- Vizcaya
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

DIXIE 50 mg Spot-On Cats

Fipronil

3. STATEMENT OF ACTIVE SUBSTANCE AND OTHER INGREDIENTES

Each pippete of 0.5 ml contains:

Active substance:
Fipronil……..50 mg
Excipients:
Butylhydroxyanisole (E320)……...0.10 mg
Butylhydroxytoluene (E321)……. 0.05 mg

Spot-on solution

Clear, colourless to yellow solution.

4. 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.'

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

6 ADVERSE REACTIONS

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

Among the extremely rare suspected adverse reactions, transient cutaneous reactions at the application site (skin discoloration, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs), vomiting or respiratory signs have been observed after use.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats.

8. DOSAGE FOR EACH SPECIES, ROUTE 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 PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of the children.

This veterinary medicinal product does not require any special storage conditions

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

12. 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 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.

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

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.

Pregnancy and lactation:

Laboratory studies in rats have not produced any evidence of teratogenic or foetotoxic effects.

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Overdose (symptoms, emergency procedures, 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 4.6.). Itching may occur following treatment.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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

14. DATE ON WICH THE PACKAGE LEAFLET WAS LAST APROVED

15. OTHER INFORMATION

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

For any information about this veterinary medicinal product, please contact with the marketing authorization holder:

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