[Version 8.1,01/2017]

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

DIXIE 67 mg spot-on solution for small dogs
DIXIE 134 mg spot-on solution for medium dogs
DIXIE 268 mg spot-on solution for large dogs
DIXIE 402 mg spot-on solution for very large dogs

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

Marketing authorisation holder :

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

Manufacturer responsible for batch release:

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

AB7 SANTE
Chemin des Monges, Deume, 32450
Montgiscard
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

DIXIE 67 mg spot-on solution for small dogs
DIXIE 134 mg spot-on solution for medium dogs
DIXIE 268 mg spot-on solution for large dogs
DIXIE 402 mg spot-on solution for very large dogs

Fipronil

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT

Each single-dose (pipette) delivers:

Active substance:

DIXIE spot-on solution for dogs	Volume of unit dose (ml)	Fipronil (mg)
small dogs – 2-10 kg	0.67	67
medium dogs – 10-20 kg	1.34	134
large dogs – 20-40 kg	2.68	268
very large dogs – 40-60 kg	4.02	402

Excipients:

DIXIE spot-on solution for dogs	Butylhydroxyanisole (E320) (mg)	Butylhydroxytouene (E321) (mg)
small dogs – 2-10 kg	0.13	0.07
medium dogs – 10-20 kg	0.27	0.13
large dogs – 20-40 kg	0.54	0.27
very large dogs – 40-60 kg	0.80	0.40

4. INDICATION(S)

Treatment of existing flea (*Ctenocephalides felis*) infestations and prevention of re-infestation with fleas through insecticidal effect for up to 5 weeks. One application provides immediate and persistent insecticidal efficacy and prevents new infestations by fleas up to a maximum of 5 weeks.

The product prevents new infestations of *Rhipicephalus sanguineus* ticks from day 9 to day 23 after product application. The product has not demonstrated an immediate acaricidal effect, 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 product can be used as part of the strategy in the treatment of flea allergy dermatitis (FAD), where this has been previously diagnosed by a veterinarian.

5. CONTRAINDICATIONS

In the absence of available data, the product should not be used in puppies less than 8 weeks of age (and / or weighing less than 2 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.
This product is specifically developed for dogs. Do not use in cats, as this could lead to overdosing.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.
Among the very rare suspected adverse reactions, transient cutaneous reactions at the application site (skin discoloration, local alopecia, pruritus, erythema, capillary bleeding) 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 treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

Do not overdose.
The risk of adverse effects may increase in cases of over-dose.
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 inform your veterinary surgeon.

Alternatively, you can report via your national reporting system {national system details

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Route of administration – Spot-on use.

Dosage:

1 pipette of 0.67 ml per dog weighing over 2 kg and up to 10 kg bodyweight
1 pipette of 1.34 ml per dog weighing over 10 kg and up to 20 kg bodyweight
1 pipette of 2.68 ml per dog weighing over 20 kg and up to 40 kg bodyweight
1 pipette of 4.02 ml per dog weighing over 40 kg and up to 60 kg bodyweight
For dogs over 60 kg use two pipettes of 2.68 ml.

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

Do not use the product if you notice visible signs of deterioration.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store below 30ºC
Keep the blister in the outer carton
Do not use this veterinary medicinal product after the expiry date which is stated on the blister after Exp. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

For external use only. Do not apply the product on wounds or damaged skin.
Avoid contact with the animal's eyes. In case of accidental eye contact immediately and thoroughly flush the eyes with water.
Animals should be weighed accurately prior to treatment (See section 5).
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
The potential toxicity of the product for puppies less than 8 weeks of age in contact with a treated bitch is not documented. Special care should be taken in this case.

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

This 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 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.

Other precautions:
Fipronil may adversely affect aquatic organisms. Dogs should not be allowed to swim in watercourses for 2 days after application.

Pregnancy and lactation:

Laboratory studies in rats have not shown 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."

Interaction with other medicinal products and other forms of interaction:

Do not use simultaneously with other flea products which are applied directly onto the animal.

Overdose (symptoms, emergency procedures, antidotes):

No adverse reactions were observed in the target animal safety studies conducted when the product was administered to dogs from 8 months of age and from 9 kg of weight a dose of up to five (5X) times the recommended dose.
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.

Incompatibilities:

Not applicable.

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 product should be disposed of in accordance with local requirements.

The product should not enter water courses as this may be dangerous for fish and other aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION>

Package sizes:
Carton box containing 1,2,3,4,5,6,7,8,10,12,24,30,60,90,120 or 150 pipettes

Not all pack sizes may be marketed.

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

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