B. PACKAGE LEAFLET

PACKAGE LEAFLET

DIPTRON 67mg spot-on solution for Small Dogs
DIPTRON 134 mg spot-on solution for Medium Dogs
DIPTRON 268 mg spot-on solution for Large Dogs
DIPTRON 402 mg spot-on solution for Very Large Dogs

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

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

Manufacturers responsible of batch release

AB7 INDUSTRIES VETERINARIES
Chemin des Monges, Deume, 32450
Montgiscard
France

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

DIPTRON 67 mg spot-on solution for Small Dogs
DIPTRON 134 mg spot-on solution for Medium Dog
DIPTRON 268 mg spot-on solution for Large Dogs
DIPTRON 402mg spot-on solution for Very Large Dogs

Fipronil

3. STATEMENT OF ACTIVE SUBSTANCE AND OTHER INGREDIENTES

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

Spot on solution

4. INDICATIONS

The treatment and prevention of infestations by fleas (*Ctenocephalides* spp.,) and ticks (*Rhipicephalus* spp, *Ixodes* spp,) and as part of the treatment strategy for Flea Allergy Dermatitis, where has been previously diagnosed by a veterinary surgeon.

5. CONTRAINDICATIONS

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 in very rare cases.

Transient cutaneous reactions at the application site (skin discoloration, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported in very rare cases. Hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs), vomiting or respiratory signs have been observed in very rare cases after use.

Do not overdose.

“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).

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."

7. TARGET SPECIES

Dogs

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

Route of administration – Spot-on use.

Dosage

*1 pipette of 0.67 ml per dog weighing over 2kg and up to 10kg bodyweight

*1 pipette of 1.34 ml per dog weighing over 10kg and up to 20kg bodyweight

*1 pipette of 2.68 ml per dog weighing over 20kg and up to 40kg bodyweight

*1 pipette of 4.02 ml per dog weighing over 40kg and up to 60 kg Bodyweight

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 ADMINSITRATION

None

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of the children.

Store below 30ºC

Store in the original package.

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 WARNINGS

Special warnings for each target species

In the absence of available data, the product should not be used on puppies less than 8 weeks old (and/or weighing less than 2 kg) [for the Small Dog and single pipette presentation only.].

The product does not prevent ticks from attaching to the animals. If the animals have been treated prior to exposure to the ticks, the ticks will be started to be killed in the first 24-48 hours after attachment. This will usually be prior to engorgement, minimizing but not excluding the risk of transmission of diseases. Once dead, ticks will often drop off the animal, but any remaining ticks may easily be removed by a gentle pull.

Bathing/immersion in water within 2 days after application of the product and more frequent bathing that once a week should be avoided, as no study has been performed to investigate how this affects the efficacy of the product.

Fleas from pets often infests the animal's basket, bedding and regular resting areas such as carpets and soft furnishing which should be treated, in case of massive infestation and at the beginning of the control measures, with a suitable insecticide and vacuumed regularly.

When used as part of a strategy for the treatment of Flea Allergy Dermatitis, monthly applications to the allergic patient and to other dogs in the household are recommended.

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.

Emollient shampoos can be used prior to treatment, but reduce the duration of protection against fleas to approximately 5 weeks when used weekly after application of the product. Dogs should not be allowed to swim in watercourses for 2 days after application.

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

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.

Use during pregnancy, lactation or lay

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.

Interaction with other medicinal products and other forms of interaction

None known

Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse effects were observed in target animal safety studies where the animals received the recommended dose, three (3X) and five (5X) times the recommended dose. The risk of experiencing adverse effects (see section 4.6) 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 products should be disposed of in accordance with local requirements.

This veterinary medicinal product should not come into watercourses 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 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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