SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DIXIE 268 mg spot-on solution for large dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single-dose 2.68 ml pipette contains:

Active substance:

Fipronil	268 mg

Excipients:

Butylhydroxyanisole (E320)	0.54 mg
Butylhydroxytouene (E321)	0.27 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot on solution.
Clear solution

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

Treatment of 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.

4.3 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 2kg).

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.

4.4 Special warnings for each target species

The product does not prevent ticks from attaching to the animals. Therefore, the transmission of infectious diseases by ticks cannot be excluded. There is no data available on the effect of bath / shampoo on the efficacy of the veterinary drug in dogs. Bathing / shampoo applied before or often after treatment may reduce the effectiveness of the product.

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.

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.

To reduce re-infestation from emergence of new fleas, it is recommended that all dogs in a household be treated. Other animals living in the same household should also be treated with a suitable product.

The product will prevent new tick infestations from day 9 to day 23 after application of the product. Considering that it takes 9 days to reach sufficient efficacy, there may be gaps in the prevention of re-infestations after subsequent applications of the product.

4.5 Special precautions for use

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 4.3).
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.

4.6 Adverse reactions (frequency and seriousness)

If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier. Transient cosmetic effects such as a wet appearance or hair clumping may occur at the application site.

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.

4.7 Use during pregnancy, lactation or lay

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.

4.8 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.

4.9 Amounts to be administered and administration route

Route of administration – Spot-on use.

Dosage –

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

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

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 (see section 4.6) may however increase when overdosing, so animals should always be treated with the correct pipette size according to bodyweight.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:. Ectoparasiticides for topical use, including insecticides
ATC vet code: QP53AX15

5.1 Pharmacodynamic properties

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 felis*), ticks *(Rhipicephalus sanguineus*) in the dog.

5.2 Pharmacokinetic particulars

Absorption: After a local application of fipronil to the dog, it is slightly absorbed through the skin. Low levels of fipronil may be detected in the plasma, with a very high variability between dogs.

Distribution: 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, etc).

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole (E320)
Butylhydroxytoluene (E321)
Povidone
Polysorbate 80
Ethanol 96% (E1510)
Diethylene glycol monoethyl ether

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

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

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions

6.5 Nature and composition of immediate packaging

White opaque plastic spot-on pipettes of high density Polyethylene -extrusion material (COEX).

Each pipette is packaged in blisters composed by plastic supports (PVC-PE) to hold them and covered by a polyester / polyethylene complex.

Package sizes:
Carton box containing 1,2,3,4,5 or 6 pipettes

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

45883/4009

9. DATE OF FIRST AUTHORISATION

17 March 2021

10. DATE OF REVISION OF THE TEXT

November 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

Dispensing conditions: **Veterinary medicinal product not subject to prescription**

Approved 02 November 2023