

[Version 8.1,01/2017]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DIPTRON 268 mg spot-on solution for Large Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pipette of 2.68 ml contains:

Active substance:

Fipronil.....268 mg

Excipients:

Butylhydroxyanisole (E320) 0.54 mg

Butylhydroxytoluene (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

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.

4.3 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.

4.4 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 2kg) [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 than 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 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.

4.5 Special precautions for use

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 (See section 6.6).

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.

Other precautions

Fipronil may adversely affect aquatic organisms. Do not allow treated animals to swim in watercourses until at least 48 hours after administration.

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 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 after use 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).

4.7 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.”

4.8 Interaction with other medicinal products and other forms of interaction

None known.

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 20kg and up to 40kg 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.

4.10 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.

4.11 Withdrawal periods

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 spp.*), ticks (*Rhipicephalus spp* and *Ixodes spp*) in the dog.

The product is effective against flea infestation for approximately 2 months and against tick infestations for up to 1 month, depending on the level of challenge. Newly arriving fleas are killed within 24 hours of landing on the animal.

5.2 Pharmacokinetic properties

***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**

After topical application, the product will spread from the site of treatment to cover the entire surface of the animal within 24 hours. 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, ...).

***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%
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

Store below 30°C.
Store in the original package.

6.5 Nature and composition of immediate packaging

White opaque plastic 2.68 ml spot-on pipettes of COEX- High Density Polyethylene -Extrusion material.

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

Not all packs 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 products should be disposed of in accordance with local requirements.

DIPTRON 268 mg spot-on solution for Large Dogs 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.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 25 February 2014

Date of last renewal: 25 February 2019

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

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