SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Diptron 50 mg Spot-On solution for cats

Portugal: Diptron Fipronil 50 mg solução unção punctiforme para Gatos

Spain: Diptron Fipronilo 50 mg Solución Spot-On para Gatos

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pipette of 0.5 ml contains:

Active substance:

Fipronil……..50 mg

Excipients:

Butylhydroxyanisole (E320))…….. 0.10 mg

Butylhydroxytouene (E321))……..0.05 mg

For the full list of excipients, see section 6.

3. PHARMACEUTICAL FORM

Spot-on solution.

Clear, colourless to yellow solution

4. CLINICAL PARTICULARS

4.1 Target species

Cat.

4.2 Indications for use, specifying the target species

'Treatment and prevention of flea infestations (*Ctenocephalides felis*). Fleas present on the animal at the time of the veterinary medicinal product application will be killed within 48hours. The veterinary medicinal product has persistent insecticidal efficacy lasting for 4 weeks against C*tenocephalides felis* fleas.

Treatment and prevention of tick infestations (*Rhipicephalus turanicus*). Ticks present on the animal at the time of the veterinary medicinal product application will be killed within 48 hours. The veterinary medicinal product has persistent acaricidal efficacy for 4 weeks against *Rhipicephalus turanicus* ticks.'

4.3 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.

4.4 Special warnings for each target species

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 veterinary medicinal 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."

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 veterinary medicinal 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 veterinary medicinal product can cause mucous membrane and eye irritation. Therefore, contact of the veterinary medicinal 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.

4.6 Adverse reactions (frequency and seriousness)

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)

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

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.

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

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.

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) in the cat.

5.2 Pharmacokinetic properties

*Absorption

After local application of the veterinary medicinal product in the cat, absorption of

fipronil through the skin is negligible.

*Distribution

After topical application, the veterinary medicinal product will spread from the site of treatment to cover the entire surface of the animal. 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 K25
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

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

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.

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

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.

7. MARKETING AUTHORISATION HOLDER

Sinergic Chemical S.L.
C/ Velázquez Nº 64, 4º Izq
28001 Madrid
Spain

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: DD month YYYY

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

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