Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Zeronil 50 mg Spot-on Solution for cats

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One 0.5 ml pipette contains:
Active substance:
Fipronil 50 mg
Excipients:
Butylhydroxyanisole E320 0.1 mg
Butylhydroxytoluene E321 0.05 mg
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Spot-on solution.
Clear, pale amber solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cats.

4.2 Indications for use, specifying the target species

Treatment of flea (*Ctenocephalides* spp.) and tick (*Rhipicephalus sanguineus* and *Ixodes ricinus*) infestations.

Insecticidal efficacy against new infestations with adult fleas persists for 2 months. The product has a persistent acaricidal efficacy for 1 month against ticks (*Rhipicephalus sanguineus*, *Ixodes ricinus*, *Dermacentor reticulatus*). For *Ixodes ricinus* and *Rhipicephalus sanguineus*, ticks will normally be killed within the first 48 hours following first application of the product. For established infestations of *Dermacentor reticulatus*, an immediate acaricidal effect has not been demonstrated. However, ticks will normally be killed within a week following first application of the product.
The product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD) where this has been previously diagnosed by a veterinary surgeon.

4.3 Contraindications

In the absence of available data, the product should not be used on kittens less than 2 months 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 drug reactions and even death could occur.
Do not use in cases of hypersensitivity to the active substance or to any of excipients.

4.4 Special warnings for each target species

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.

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

Avoid frequent swimming/bathing or shampooing the animal because the maintenance of effectiveness of the product in these cases has not been tested.

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

4.5 Special precautions for use

Special precautions for use in animals

Avoid contact with the animal’s eyes. In the case of accidental eye contact, immediately and thoroughly flush the eyes with water.

Do not apply the product on wounds or damaged skin.

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.

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

This product can cause mucous membrane and eye irritation. Therefore, contact between the product and the mouth or eyes should be avoided.
In the case of accidental eye contact, immediately and thoroughly flush the eyes with water. If eye irritation persists seek medical advice and show the package leaflet or the label to the physician.
Do not smoke, drink or eat during application.
Avoid contents coming into contact with the skin. If this occurs, wash hands with soap and water. Wash hands after use.
Animals or operators with a known hypersensitivity to fipronil or excipients (see section 6.1) should avoid contact with the veterinary medicinal product.
Treated animals should not be handled until the application site is dry, and children should be kept away from treated animals 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

The alcohol carrier may have adverse effects on painted, varnished or other household surfaces or furnishings.
This product is flammable. Keep away from heat, sparks, open flame or other sources of ignition.

4.6 Adverse reactions (frequency and seriousness)

The frequency of adverse reactions is defined using the following convention:
- Very common (more than 1 in 10 animals displaying adverse reactions 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).

If licking occurs, a brief period of hypersalivation 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 (squamosis, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurologic symptoms (hyperaesthesia, depression, nervous symptoms) or vomiting have been observed after use.

4.7 Use during pregnancy, lactation or lay

Laboratory studies using fipronil have not shown any evidence of teratogenic or embryotoxic effects. Studies have not been carried out with this product in pregnant and lactating queens. Use in pregnancy and lactation only in accordance with professional veterinary advice and a benefit/risk assessment.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

Route of administration and dosage:

External use only.
Administer by topical application to the skin according to the bodyweight as follows:
1 pipette of 4.02 ml per dog weighing over 40 kg and up to 60 kg bodyweight.
An appropriate combination of pipettes should be used for dogs weighing > 60 kg bodyweight.

Method of administration:

Remove the pipette from the sachet. Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents are within the main body of the pipette. Snap back the tip.

Part the pet's coat until the skin is visible. Place the tip of the pipette directly against the bared skin and squeeze gently to empty its contents at two points along the dog's back, preferably at the base of the head and between the shoulder blades, emptying approximately half the volume at each site. Squeeze the pipette several times to ensure dosing is complete.

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.

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. Scaling and crystalline deposits on the hairs may also be observed at the site of application for up to 48 hours.

Treatment schedule:

For optimal control of flea and/or tick infestation the treatment schedule can be based on the local epidemiological situation.

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 aged 2 months and older and weighing about 1 kg treated at five times the recommended dose over 3 consecutive months. The risk of adverse effects may increase in cases of over-dose.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use.
ATCvet code: QP53AX15

5.1 Pharmacodynamic properties

Fipronil is an insecticide and acaricide belonging to 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 cell membranes. This results in uncontrolled activity of the central nervous system and death of insects or acarids.
Fipronil exhibits an insecticidal and acaricidal activity against fleas (*Ctenocephalides* spp.), ticks (*Rhipicephalus* spp, *Dermacentor* spp, *Ixodes*spp including *Ixodes ricinus*) in the dog.
Fleas will be killed within 48 hours. Ticks will usually be killed within 48 hours after contact with fipronil, however if ticks of some species (*Dermacentor* spp) are already present when the product is applied, all of the ticks may not be killed within the first 48 hours.

5.2 Pharmacokinetic particulars

Absorption
Absorption of fipronil through the skin is negligible.

Distribution
After topical application, the product will spread from the site of treatment to cover the entire surface of the animal within 24-48 hours.

Biotransformation
Fipronil is mainly metabolised to its sulfone derivative, 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
Benzyl alcohol E1519
Diethylene glycol monoethyl ether

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in a dry place. Store in the original container.

6.5 Nature and composition of immediate packaging

A 0.5mlwhite pipette composed of a heat-formed shell of a polypropylene/cyclic olefin copolymer/polypropylene layer and a polyethylene/ethylene vinyl alcohol/polyethylene layer.

A Cardboard box with 1, 2, 3, 4, 6, 8, 9, 10, 12, 15, 18, 20, 21, 24, 30, 60, 90 or 150 pipettes in individual foil sachets.
Italy : 1, 3, 6, 9, 12, 21 & 30 pipettes in individual foil sachets.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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.

Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited
Loughrea
Co. Galway
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10987/094/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 July 2012
Date of last renewal: 16 February 2017

10 DATE OF REVISION OF THE TEXT

August 2018