SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanonil Spot-on Solution Dog 402 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One 4.02 ml pipette contains:
Active substance:
Fipronil 402 mg

Excipients:
Butylhydroxyanisole E320 0.804 mg
Butylhydroxytoluene E321 0.402 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

Dogs.

4.2 Indications for use

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

Insecticidal efficacy against new infestations with adult fleas persists for 8 weeks.
The product has a persistent acaricidal efficacy for 4 weeks against ticks (*Rhipicephalus sanguineus*, *Ixodes ricinus*, *Dermacentor reticulatus*).
If ticks of some species (*Dermacentor reticulatus*) are already present when the product is applied, all of the ticks may not be killed within the first 48 hours.

4.3 Contraindications

Do not use on puppies less than 8 weeks old and /or weighing less than 40 kg.
Do not use on sick (e.g. 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 on animals with known hypersensitivity to the active substance or to any of excipients.

4.4 Special warnings for each target species

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

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.

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.

For optimal control of flea infestation in multi-pet household, all dogs and cats in the household should be treated with a suitable insecticide.

4.5 Special precautions for use

Special precautions for use in animals

Animals should be weighed accurately prior to treatment.

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

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

Do not apply the product on wounds or damaged skin.

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

Keep pipettes in original packaging until ready to use.
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 fingers. If this occurs, wash hands with soap and water. Wash hands after use.
Ingestion of the product is harmful. Prevent children getting access to the pipettes and discard the used pipettes immediately after applying the product. In case of accidental ingestion of product seek medical advice immediately.
Animals or people with a known hypersensitivity (allergy) to fipronil or any of the other ingredients should avoid contact with the product.
Treated animals should not be handled until the application site is dry, and children should not be allowed to play with 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

Fipronil may adversely affect aquatic organisms. Dogs should not be allowed to swim in water courses for 2 days after application.
The product may have adverse effects on painted, varnished or other household surfaces or furnishings.

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.
Among the extremely rare suspected adverse reactions, transient cutaneous reactions on the application site (skin discoloration, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use.
Exceptionally, hypersalivation, reversible neurologic symptoms (hyperesthesia, depression, nervous symptoms), vomiting or respiratory symptoms have been observed after use.

4.7 Use during pregnancy and lactation

Laboratory studies using fipronil have not shown any evidence of teratogenic or embryotoxic effect. Studies have not been carried out with this product in pregnant and lactating bitches. 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 interaction

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.
For dogs over 60 kg, use two pipettes of 2.68 ml.

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.

Application of the solution as directed minimises the possibility that the animal will lick the solution off.

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 usually disappear within 24 - 48 hours post application. Crystals may be seen on the hair and slight scaling may occur within 24 – 48 hours after application.

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

The minimum interval between two treatments is 4 weeks.

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

No adverse effects were observed in target animal safety studies in 8 week-old puppies, growing dogs and dogs weighing about 2 kg treated with 5 times the therapeutic dose once a month for 3 consecutive months. The risk of adverse effects (see section 4.6) may increase in cases of overdose.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL 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 24 h. Ticks will usually be killed within 48 h 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

Fipronil is mainly metabolised to its sulfone derivative (RM1602), which also possesses insecticidal and acaricidal properties. The concentrations of fipronil on the hair decrease with time.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole E320
Butylhydroxytoluene E321
Benzyl alcohol
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 in the original package.

6.5 Nature and composition of immediate packaging

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

Box with 1, 2, 3, 4 or 6 pipettes in individual foil sachets.

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 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

EU Pharmaceuticals Ltd
37 Geraldine Road
London
SW18 2NR

8. MARKETING AUTHORISATION NUMBER

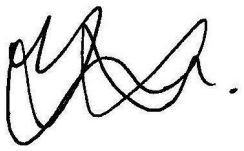
Vm 39787/4034

9. DATE OF FIRST AUTHORISATION

01 October 2018

10. DATE OF REVISION OF THE TEXT

May 2023



Approved: 10 May 2023