1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fipnil 402 mg Spot-on Solution for extra large dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One 4.02 ml pipette contains:

Active substances:
Fipronil 402 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butylhydroxyanisole E320	0.804 mg
Butylhydroxytoluene E321	0.402 mg
Benzyl alcohol E1519	
Diethylene glycol monoethyl ether	

Clear, pale amber solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each 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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product.
The veterinary medicinal 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.

3.3 Contraindications

Do not use on puppies less than 2 months old or puppies or dogs weighing less than 2 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 veterinary medicinal 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 excipients.

3.4 Special warnings

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

The veterinary medicinal 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.

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

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

3.5 Special precautions for use

Special precautions for safe use in the target species:
Animals should be weighed accurately prior to treatment to ensure that the correct size of pipette is applied.
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 veterinary medicinal product on wounds or damaged skin.
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:
This veterinary medicinal product can cause mucous membrane and eye irritation. Therefore, contact between the veterinary medicinal 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 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.

Special precautions for the protection of the environment:
Fipronil may adversely affect aquatic organisms. Dogs should not be allowed to swim in water courses for 2 days after application.

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

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersalivation [1] Application site reactions [2] (Skin Discolouration, Alopecia, Pruritus, Erythema) Generalised itching General hair loss Neurological disorders [3] (Hyperaesthesia, Central nervous system depression, Neurological symptoms) Vomiting Respiratory tract disorder

[1] If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.
[2] Transient cutaneous reactions.
[3] Reversible symptoms.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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 only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Spot-on use.

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 dog'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 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.

Care should be taken to avoid excessive wetting of the hair with the veterinary medicinal 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse effects were observed in target animal safety studies in 2 month-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 may increase in cases of overdose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QP53AX15

4.2 Pharmacodynamics

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 veterinary medicinal product is applied, all of the ticks may not be killed within the first 48 hours.

4.3 Pharmacokinetics

Absorption:
Absorption of fipronil through the skin is slight.

Distribution:
After topical application, the veterinary medicinal 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

A 4.02 ml white 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.
Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

This veterinary medicinal product should not enter water courses as fipronil may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10987/095/004

8. DATE OF FIRST AUTHORISATION

03/02/2012

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

06/11/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).