

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTLINE SPOT ON CAT 10% w/v Spot On Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Fipronil.....10% w/v
Butylhydroxyanisole.. E320.....0.02% w/v
Butylhydroxytoluene.. E321.....0.01% w/v
Non-aqueous vehicle.....qs.....to 100%

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Spot-on solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cat.

4.2 Indications for use, specifying the target species

The treatment and prevention of flea and tick infestations in cats. The product controls infestations with *Felicola subrostratus* biting lice on cats.

4.3 Contra-indications

Do not use on kittens less than 8 weeks old and/or weighing less than 1 kg. Do not use on animals that are unwell, are undergoing treatment for, or are recovering from illness..

Do not use in rabbits, as adverse drug reactions and even death could occur.

Do not use in animals with known hypersensitivity to the active substance or to any of the other ingredients.

4.4 Special warnings for each target species

When treating infestations of lice, all in-contact cats should be treated with an appropriate product at the same time.

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.

There may be an attachment of single ticks. For this reason transmission of

infectious diseases cannot be completely excluded if conditions are unfavourable.

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.

FRONTLINE Spot On Cat prevents re-infestation with all stages of *Rhipicephalus* spp. *Dermacentor* spp. and *Ixodes* spp. ticks for up to one month, depending on the level of environmental challenge.

No data on the effect of bathing/shampooing on the efficacy of the product in cats are available. However, based on information available for dogs shampooed from 2 days after application of the product, it is not recommended to bath animals within 2 days after application of the product.

4.5 Special precautions for use

(i) Special precautions for use in animals

For external use only.

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.

Avoid contact with the animal's eyes.

Do not overdose.

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

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

This product can cause mucous membrane and eye irritation. Therefore, contact of the product with mouth and eyes should be avoided.

People with a known hypersensitivity to insecticides or alcohol should avoid contact with the product.

Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.

After accidental ocular exposure the eye should be rinsed carefully with plain water.

Wash hands after use.

Do not smoke, drink or eat during application.

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.

(iii) Other precautions

The alcohol carrier 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 excessive salivation/drooling may be observed due mainly to the nature of the solvents in the product.

Among the extremely rare suspected adverse reactions, short-lived skin reactions at the application site (scaling, local hair loss, itchiness, reddening) and general itchiness or hair loss have been reported after use. Exceptionally, excessive drooling, reversible nervous signs including hyperaesthesia (increased sensitivity to light and sound or overexcited or unusual behavior), depression, or vomiting 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 using fipronil have not shown any evidence of toxicity to the embryo or developmental abnormalities in the young.

The safety of the product was demonstrated in breeding, pregnant and lactating queens treated with multiple consecutive doses with up to 3 times the maximum recommended dose.

The product can be used during pregnancy and lactation.

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: By topical application to the skin.
Dosage: 1 pipette of 0.5 ml per cat (approximately 7.5 – 15 mg/kg)
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 against the skin and squeeze gently to empty its contents directly onto the skin, preferably at two spots, one at the base of the skull and a second 2-3cms further back.

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.

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

No undesirable effects were observed in target animal safety studies in cats and kittens aged 8 weeks and older and weighing about 1 kg treated once a month at five times the recommended dose for six consecutive months. The risk of experiencing adverse effects may however increase with overdosing (see section 4.6.). Itching may occur following treatment.

Overdose application of the product will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will disappear within 24 hours post application.

4.1 Withdrawal periods

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other ectoparasiticides for topical use.

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. *Dermacentor* spp. and *Ixodes* spp.) and lice (*Felicola subrostratus*) in the cat.

The product is effective against fleas for up to 5 weeks in cats, depending on the level of environmental challenge. Newly arriving fleas are killed within 24 hours of landing on the animal.

5.2 Pharmacokinetic properties

*Absorption

After local application of the product in the cat, absorption of fipronil through the skin is negligible.

*Distribution

After application, 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

In 'in vitro' studies with subcellular liver fractions, the principal metabolite is the sulfone derivative of fipronil. However, this may be of limited relevance 'in vivo' as fipronil is poorly absorbed in the cat.

*Elimination

The concentrations of fipronil on the hair decrease with time to attain a level of approximately $1 \mu\text{g.g}^{-1}$ two months after treatment.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyvidone K17
Polysorbate 80
Ethanol
Diethylene Glycol Monoethyl Ether

6.2 Major incompatibilities

No known incompatibility.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Store in the original package.
Store in a dry place.
Do not store above 300C.
Flammable.

6.5 Nature and composition of immediate packaging

Heatformed shell containing an extractable volume of 0.5ml : double foiled film composed of polypropylene coloured on its external surface with blue Pantone 293C and a copolymer of polyacrylonitrile-methacrylate in contact with the solution (200µm/350µm).

Opercule: triple foiled film composed of polyethylene terephthalate opacified with titanium dioxide, aluminium and copolymer of polyacrylonitrile-methacrylate in contact with the solution (12µm/12µm/35µm).

Frontline Spot On Cat is available in the following presentations:

- Blister card containing 1 pipette of 0.50ml of the solution.
- Foil blister strips containing 3 pipettes of 0.50ml of the solution. The foil blister strips are packed into cartons containing 3 or 6 pipettes.

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 containers.

7. MARKETING AUTHORISATION HOLDER

Merial Animal Health Limited
PO Box 327
Sandringham House
Harlow Business Park
Harlow
Essex
CM19 5TG

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4133

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27 November 2006

10. DATE OF REVISION OF THE TEXT

November 2015

ANY OTHER INFORMATION REQUIRED BY THE SECRETARY OF STATE

Not applicable.

Approved: 20 November 2015

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