

FIPRONIL 9.8% w/v (S)-METHOPRENE 11.8% w/v FRONTLINE®

PLUS



Spot-on solution.

For Cats
For external use only

Composition:

Frontline Plus (Cats) contains:
Fipronil 9.8%
(S)-Methoprene.....11.8%

Keep out of reach of children.

Not for human use; for animal treatment only.

WARNING: To be sold by retail on prescription of Registered Medical Practitioner only.

Indications:

- To be used against infestation with fleas, alone or in association with ticks and/or biting lice.
- Elimination of fleas (*Ctenocephalides* spp.). Insecticidal efficacy against new infestations with adult fleas persists for 4 weeks. Prevention of the multiplication of fleas by inhibiting the development of eggs (ovicidal activity), larvae and pupae (larvicidal activity) originating from eggs laid by adult fleas for 6 weeks after application.
- Elimination of ticks (*Ixodes ricinus*, *Dermacentor variabilis*, *Rhipicephalus sanguineus*). The product has a persistent acaricidal efficacy for up to 2 weeks against ticks (based on experimental data).
- Elimination of biting lice (*Felicola subrostratus*).

The product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).

Fipronil kills fleas within 24 hours and ticks and lice within 48 hours post-exposure.

Dose and method of administration

One pipette of 0.5ml per cat, corresponding to a minimum recommended dose of 5mg/kg for fipronil and 6mg/kg for (S)-Methoprene, by topical application to the skin.

Method of administration

Remove one pipette from the foil pack. Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette. Snap back the tip. Part the coat on the back of the animal at the base of the neck in front of the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin in one spot.

Contraindications

The product should not be used on kittens less than 8 weeks old and/or weighing less than 1kg. Do not use on sick (e.g. systemic diseases, fever) or convalescent animals. Do not use in rabbits, as adverse drug reaction with even mortality could occur. In the absence of safety studies, the minimum treatment interval is 4 weeks.

Adverse Reactions

Among the very rare suspected adverse reactions, transient skin reactions on the application site (scaling, local hair loss, itching, redness) and general itching or hair loss have been reported after use. Excessive salivation, reversible nervous signs (increased sensitivity to stimulation, depression, other nervous signs) or vomiting have also been observed after use.

If licking occurs, a brief period of excessive salivation may be observed due mainly to the nature of the carrier. Do not overdose.

Warnings for target species

Avoid the contact with the animal's eyes.

Precautions for use

Special precautions for use in animals

It is important to make sure that the product is applied to an area where the animal cannot lick off and to make sure that animals do not lick each other following treatment.

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

There may be an attachment of single ticks. For this reason a transmission of infectious diseases cannot be completely excluded if conditions are unfavorable.

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.

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

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

Animals or operators with a known hypersensitivity to insecticides or alcohol should avoid contact.



927217

PACK OPS LYON GRAPHIC ARTWORK APPROVAL



<p>Code: 0 053 927217</p> <p>PRODUCT: NOT FTL PLUS CHAT X3 RECTO</p> <p>COUNTRY: INDE (IN)</p> <p>Dimensions à plat (mm): 240 x 80</p> <p>Dimensions plié(e)s: 120 x 80</p>	<p>VERSION PTG : 0037 Version : A 180316</p> <p>INITIALS: CS - Composer RH</p> <p>VERSION - DATE: A 23/03/21 11h00 B 20/05/21 15h00</p>	<p>COLORS</p> <p style="background-color: black; color: white; padding: 5px; text-align: center;">Noir/Black</p> <p>! Please use the official PANTONE® (P) matching system for an accurate color representation.</p>
<p>PRINTED BASIS CODE (if applicable): NA</p>	<p>CANCEL AND REPLACE: 0 053 920972</p>	

Marketing approval:

COMPLETE NAME:

DATE + SIGNATURE:

Regulatory approval:

COMPLETE NAME:

DATE + SIGNATURE:

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TECHNICAL NOTE(S) - INFO(S) TECHNIQUE

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with Frontline Plus Spot On cat. Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water. After accidental exposure the eye should be rinsed carefully with pure water. Wash hands after use. 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 are not allowed to sleep with owners, especially children. Do not smoke, drink or eat during application.

Use during pregnancy, lactation

The product can be used during pregnancy and lactation.

Drug interactions

None known

Overdose

The risk of experiencing adverse effects may increase with overdosing. No undesirable effects were observed in target animals safety studies in cats and kittens aged 8 weeks and older and weighing about 1kg treated once a month at five times the recommended dose for six consecutive months. 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.

Pharmacodynamics and pharmacokinetic properties

The product is an insecticidal and acaricidal solution for topical use, containing an association of an adulticidal active ingredient, fipronil, in combination with an ovicidal and larvicidal active ingredient, (S)-Methoprene.

Pharmacodynamics properties

Fipronil is an insecticide and acaricide belonging to the phenylpyrazole family. It acts by interacting with ligand-gated chloride channels, in particular those gated by the neurotransmitter gamma-aminobutyric acid (GABA), 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 acarines. Fipronil kills fleas within 24 hours, ticks (*Dermacentor variabilis*, *Rhipicephalus sanguineus*, *Ixodes scapularis*, *Ixodes ricinus*, *Haemaphysalis longicornis*, *Haemaphysalis flava*, *Haemaphysalis campanulata*) and lice within 48 hours post-exposure.

(S)-Methoprene is an insect growth regulator (IGR) of the class of compounds known as juvenile hormone analogues that inhibit the development of immature stages of insects. This compound mimics the action of juvenile hormone and causes impaired development and death of the developing stages of fleas. The on-animal ovicidal activity of (S)-Methoprene results from either direct penetration of the eggshell of newly laid eggs or from absorption through the cuticle of the adult fleas. (S)-Methoprene is also effective in preventing flea larvae and pupae from developing, which prevents contamination of the environment of treated animals with the immature stages of fleas.

Pharmacokinetic particulars

Studies of metabolism of fipronil have demonstrated that the major metabolite is the sulfone derivative of fipronil.

(S)-Methoprene is extensively degraded into carbon dioxide and acetate that are subsequently incorporated into endogenous materials.

The pharmacokinetic profiles after topical application of fipronil (S)-Methoprene in combination were studied in cats in comparison to intravenous dosing of fipronil or (S)-Methoprene alone. This established absorption and other pharmacokinetic parameters under conditions mimicking clinical practice. The topical application, with additional potential oral exposure from licking, resulted in overall systemic absorption of fipronil (18%) with a mean maximum concentration (C_{max}) of approximately 100mg/ml fipronil and 13mg/ml of fipronil sulfone in plasma.

Peak fipronil plasma concentrations are rapidly attained (mean t_{max} approximately 6 h) and decline with a mean terminal half-life of approximately 25h.

Fipronil is slightly metabolized to fipronil sulfone in cats.

Plasma concentrations of (S)-Methoprene were generally below the limit of quantitation (20mg/ml) in cats after topical application.

Both (S)-methoprene and fipronil, together with its major metabolite, are well-distributed in the hair coat of cats within one day after application. The concentrations of fipronil, fipronil sulfone and (S)-Methoprene in the hair coat decrease with time and are detectable for at least 59 days after dosing. Parasites are killed through contact rather than by systemic exposure.

No pharmacological interaction between fipronil and (S)-Methoprene was noted.

Incompatibilities: None known

Storage and handling:

Do not store above 30°C. Store in the original package. Do not use after the expiry date stated on the package after EXP. The expiry date refers to the last day of the month.

Special precautions for the disposal of unused products or waste materials, if any:

Fipronil and (S)-methoprene may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers. Medicines should not be disposed of via wastewater or household waste. Ask your veterinarian how to dispose of medicines no longer required. These measures should help to protect the environment.

Shelf life: 36 months

Withdrawal period: Not applicable

Manufactured by:

M/s. Boehringer Ingelheim Animal Health France SCS, 4 Chemin du calquet, 31000 Toulouse, France.

Importer:

M/s. Boehringer Ingelheim India Pvt Ltd, Bld No.D-5, Gala No: 1 to 5, Shree Arianth Compound Ground Floor, Reti Bunder Road, Kalher, Bhiwandi, Tal: Bhiwandi – 15 (Thane-Zone5), Pin: 421302, India

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