

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Frontline Spray 0.25 %w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Fipronil 0.25 % w/v

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Cutaneous spray, solution.

A clear solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs, cats.

4.2 Indications for use, specifying the target species

The treatment and prevention of infestation by fleas and the treatment and control of ticks in dogs and cats.

The product rapidly controls infestations with *Trichodectes canis* biting lice of dogs and *Felicola subrostratus* biting lice of cats.

Treatment with Frontline Spray has been shown to significantly reduce the incidence of flea allergy dermatitis in both dogs and cats.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance.

Do not use on sick (systemic diseases, fever...) or convalescent animals. Do not use Frontline Spray in rabbits as adverse reactions and even death could occur.

4.4 Special warnings for each target species

For external use only.

Avoid spraying in the animals' eyes.

Do not spray directly onto areas of broken skin.

Ticks will usually detach from the treated host within 24 to 48 hours after infestation, without having had a blood meal. However, some ticks may attach. For this reason, transmission of infectious diseases by ticks cannot be completely prevented.

Treatment of bedding, carpets and soft furnishings with a suitable insecticide will aid reduction in environmental challenge and maximise the duration of protection against re-infestation provided by Frontline Spray. Frontline Spray is not suitable for direct treatment of the environment.

For optimum efficacy, it is not recommended to bathe or shampoo animals in the two days prior to or following treatment with Frontline Spray. Bathing or shampooing up to four times in two months has been shown to have no significant effect on the residual efficacy of Frontline Spray. Monthly treatment is recommended when more frequent shampooing is carried out.

4.5 Special precautions for use

Special precautions for use

Do not overdose.

It is important to make sure that animals do not lick each other following treatment. Dogs should not be allowed to swim in watercourses for 2 days after application (see Section 6.6)

There may be an attachment of single ticks. For this reason a transmission of infectious diseases cannot be completely excluded if conditions are unfavourable. Keep treated animals away from fires or other sources of heat, and surfaces likely to be affected by the alcohol spray, for at least 30 minutes following spraying and until the fur is totally dry. Do not spray on a naked flame or any incandescent material. Puppies and kittens from 2 days of age may be safely treated.

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 of the product with mouth and eyes should be avoided.

Animals or operators with a known hypersensitivity to insecticides or alcohol should avoid contact with Frontline Spray. 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. If irritation occurs, seek medical advice. People with known sensitivity or asthma may be particularly sensitive to Frontline Spray. Do not use product if you have previously experienced a reaction to it.

Treated animals should not be handled until the fur is dry, and children should not be allowed to play with treated animals until the fur 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.

Spray animals in the open air or a well ventilated room.

Do not breathe spray.

Do not smoke, drink or eat during application.

Wear PVC or nitrile gloves during treatment of animals. It is recommended to wear a waterproof apron for the protection of clothing. If clothing becomes heavily wetted with FRONTLINE Spray, it should be removed and washed before re-use.

Dispose of gloves after use and then wash hands with soap and water.

Treatment of multiple animals: Good ventilation is particularly important where several animals are to be treated. Treat multiple animals outside, or reduce the build up of vapour by removing the animals from the treatment room while the alcohol is evaporating and ensure that the treatment room is well ventilated between individual treatments. In addition, ensure that the drying room is well ventilated and avoid housing several recently treated animals within the same air space. Do not confine animals in an enclosed space or pet carrier until the coat is dry.

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 (erythema, pruritus or alopecia) have been reported after use. Exceptionally, hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs), vomiting or respiratory signs have been observed after use.

4.7 Use during pregnancy, lactation or lay

Laboratory studies did not reveal any teratogenic effect of fipronil in the rat and rabbit.

The formulation is very well tolerated by puppies following treatment of the lactating bitch.

Data are not available on treatment of pregnant queens or nursing queens.

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: mechanical pump spray for external use.

Method of administration: Adjust the pump nozzle to spray setting. Spray the entire body of the animal, and apply from a distance of approximately 10 - 20 cm. Apply against the lay of the hair and make sure that the entire coat of the animal is dampened. Ruffle the coat, especially in long haired animals, so that the product penetrates down to the skin. For treatment of the head region, and when treating young or nervous pets, application may be carried out by spraying onto a gloved hand and rubbing the product into the coat. Allow to dry naturally. Do not towel dry.

Posology: In order to dampen the coat down to the skin, depending on the length of hair, apply 3 to 6 ml per kg bodyweight, (7.5 to 15 mg of active ingredient per kg bodyweight) i.e. 6 to 12 pump applications per kg bodyweight of the 100 ml presentation, or 2 to 4 pump applications of the 250 ml presentation.

The product is active for up to 3 months against fleas in dogs, and up to 2 months in cats, depending on the environmental challenge. It is active for up to 4 weeks against *Ixodes* species ticks in dogs and cats depending on the level of environmental challenge.

The 100 ml pack contains approximately 8 treatments for a short haired medium sized cat (4 kg). The 250 ml pack contains approximately 4 treatments for a short haired medium sized dog (20 kg).

Properties: The formulation contains a coating agent. Therefore, spraying builds up a film and makes the fur glossy.

In the absence of safety studies, the minimum treatment interval is 4 weeks.

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

The risk of experiencing adverse effects (see section 4.6) may increase when overdosing, so animals should always be treated with the correct dose according to bodyweight.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiparasitic products, insecticides and repellents, ectoparasiticides for topical use, incl. insecticides, fipronil.

ATC vet code: QP53AX15

Fipronil is an insecticide and acaricide from 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.

5.1 Pharmacodynamic properties

Fipronil exhibits insecticidal and acaricidal activity against fleas (*Ctenocephalides* spp), ticks (*Rhipicephalus* spp., *Ixodes* spp.) and lice (*Trichodectes* spp. and *Felicola* spp.) in the dog and cat and may aid in the control of a number of other ectoparasite species in dogs and cats including *Neotrombicula autumnalis*, *Sarcoptes* spp. and *Cheyletiella* spp.

5.2 Pharmacokinetic particulars

Absorption

The amount of fipronil absorbed by the skin in the dog, after application of the spray to the coat and skin is extremely slight to negligible.

Distribution

The persistence of fipronil on the hair is very long (on average 52.5 ± 11.5 days), given that the limit of quantification of the assay method is $0.25 \mu\text{g/g}$.

Biotransformation

In all species fipronil is mainly metabolised to its sulphone derivative (RM 1602), which also possesses insecticidal and acaricidal properties.

The RM 1602 detected on the hair after spray application in dogs may be explained by its presence in the original raw material.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Copovidone
Isopropyl alcohol
Purified water

6.2 Major incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

Keep away from sources of ignition.
Protect from sunlight.

6.5 Nature and composition of immediate packaging

(i) 125 ml spray bottle (filled to 100 ml) in high density polyethylene, fitted with a mechanical pump spray delivering 0.5 ml per spray (plunger in low density polyethylene). "Safety stopper" with polyethylene seal.

(ii) 250 ml stoppered spray bottle in high density polyethylene, with an attached mechanical pump spray delivering 1.5 ml per spray (plunger in low density polyethylene).

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 product 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

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10454/050/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th July 1995

Date of last renewal: 16th April 2010

10 DATE OF REVISION OF THE TEXT

July 2018