1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frontline Spray 0.25 w/v cutaneous spray, solution for dogs and cats.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Fipronil 0.25 w/v

Excipients:

Qualitative composition of excipients and other constituents
Copovidone
Isopropyl alcohol
Purified Water

Clear, colourless liquid.

3. CLINICAL INFORMATION

3.1 Target species

Dogs, cats.

3.2 Indications for use for each 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 the veterinary medicinal product has been shown to significantly reduce the incidence of flea allergy dermatitis in both dogs and cats.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use on sick (systemic diseases, fever…) or convalescent animals. Do not use the veterinary medicinal product in rabbits as adverse reactions and even death could occur.

3.4 Special warnings

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 the veterinary medicinal product. The veterinary medicinal product 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 the veterinary medicinal product. Bathing or shampooing up to four times in two months has been shown to have no significant
effect on the residual efficacy of the veterinary medicinal product. Monthly treatment is recommended when more frequent shampooing is carried out.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 5.5)
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.
People with known hypersensitivity to insecticides or alcohol should avoid contact with the veterinary medicinal 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. If irritation occurs, seek medical advice. People with known sensitivity or asthma may be particularly sensitive to the veterinary medicinal product. 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.
Personal protective equipment consisting of PVC or nitrile gloves and a waterproof apron should be worn when handling the veterinary medicinal product. If clothing becomes heavily wetted with the veterinary medicinal product, 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs, cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site reaction (erythema, pruritus or alopecia)[1] Hypersalivation[2], vomiting. Respiratory signs. Neurological signs (hyperaesthesia, depression)[3]

[1] Transient.
[2] If licking occurs.
[3] Reversible. Other nervous signs.

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 in rat and rabbit have not produced any evidence of teratogenic effects. The formulation is very well tolerated by puppies following treatment of the lactating bitch. The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

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.

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

The risk of experiencing adverse effects (see section 3.6) may increase when overdosing, so animals should always be treated with the correct dose according to bodyweight.

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 IMMUNOLOGICAL INFORMATION

4.1 ATCvet code:
QP53AX15

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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 µg/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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

Keep away from sources of ignition.
Protect from direct sunlight.

5.4 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).

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.

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.

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

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10454/050/001

8. DATE OF FIRST AUTHORISATION

07 July 1995

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

27 August 2024

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).