

FLEASCREEN® COMBO

Fipronil, (S)-methoprene

Fleascreen® Combo 50mg/60mg Spot On Solution for Cats and Ferrets

SPECIES

Cats, Ferrets

THERAPEUTIC INDICATION

Pharmaceuticals: Ectoparasitocides: For cats

ACTIVE INGREDIENT

Fipronil, (S)-methoprene

PRODUCT/PRODUCT INDEX

Fleascreen Combo Spot On Cat

PRESENTATION

Spot on solution, light yellow to yellow clear liquid. 1 pipette contains 50mg fipronil and 60mg s-methoprene.

USES

In cats: To be used against infestations 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 six 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.
- 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), where this has been previously diagnosed by a veterinary surgeon.

In ferrets: To be used against infestations with fleas, alone or in association with ticks:

- 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.
- Elimination of ticks (*Ixodes ricinus*). The product has a persistent acaricidal efficacy for 4 weeks against ticks.

DOSAGE AND ADMINISTRATION

EXTERNAL USE ONLY. Administer by topical application to the skin.

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

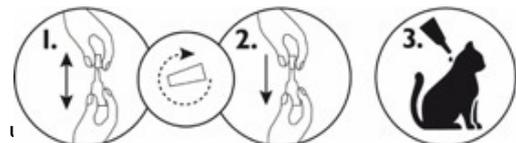
In the absence of safety studies, the minimum treatment interval is 4 weeks.

Ferrets: One pipette of 0.5 mL per ferret corresponding to a dose of 50 mg for fipronil and 60 mg for (S)-methoprene per ferret, by topical application to the skin.

The minimum treatment interval is 4 weeks.

Method of administration:

1. Remove the pipette from its packaging. Hold the pipette in an upright position, twist and pull the cap off.
2. Turn the cap around and place the other end of the cap back on the pipette. Push and twist the cap to break the seal, then remove the cap from the pipette.
3. 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 onto the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin in one spot.



In cats: The product can be used during pregnancy

The potential toxicity of the product for kittens of less than 8 weeks of age in contact with a treated queen is not documented. Special care should be taken in this case.

In ferrets: Laboratory studies in cats have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. The safety of the veterinary medicinal product has not been established in ferrets during pregnancy and lactation. Use only according to the risk-benefit assessment by the responsible veterinarian.

CONTRA-INDICATION, WARNINGS, ETC

In the absence of available data, the product should not be used on kittens less than 8 weeks old and/or weighing less than 1 kg. The product should not be used on ferrets less than 6 months old.

Do not use on sick (e.g. systemic diseases, fever) or convalescent animals.

Do not use in rabbits due to a risk of adverse reactions or even death.

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

Do not overdose.

Special precautions for use in animals

Avoid the contact with the animal's eyes.

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.

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

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.

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 in clean water.

Wash hands after use.

In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

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 are not allowed to sleep with owners, especially children.

ADVERSE REACTIONS

In cats; 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.

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. 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.

In the case of licking the administration site, a brief period of excessive salivation may be observed due mainly to the nature of the carrier.

In ferrets aged 6 months and older and treated once every 2 weeks for four treatments, at five times the recommended dose, body weight loss was observed in some animals.

INTERACTIONS

None known.

ENVIRONMENTAL SAFETY

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.

PHARMACEUTICAL PRECAUTIONS

Store in the original package in order to protect from light and moisture.

This veterinary medicinal product does not require any special temperature storage conditions.

Keep out of the sight and reach of children

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

FURTHER INFORMATION

Pharmacotherapeutic group: Ectoparasiticides for topical use, incl. insecticides

ATCvet code: QP53AX65

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.

No data on the effect of bathing/shampooing on the efficacy of the product in cats and ferrets are 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.

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 and ticks (*Dermacentor reticulatus*, *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.

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.

The product does not prevent ticks from attaching to the animals. If the animal has been treated prior to exposure to the ticks, the tick 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.

LEGAL CATEGORY AVM-GSL

PACKAGING

Presented in pipettes, individually wrapped in foil and cardboard boxes of 3,6 or 30 pipettes.

MARKETING AUTHORISATION NUMBER

Vm 01656/4113

GTIN (GLOBAL TRADE ITEM NUMBER)

Fleascreen Combo Spot-On for Cats and Ferrets 3 pack 03838989649111

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