

FLEA SCREEN combo[®]

Fipronil,
(S)-methoprene

FLEA SCREEN combo Spot On Solution for Dogs 67mg, 134mg, 268mg, 402mg

SPECIES

Dogs

THERAPEUTIC INDICATION

Pharmaceuticals: Ectoparasiticides: For dogs

ACTIVE INGREDIENT

Fipronil, (S)-methoprene

PRODUCT/PRODUCT INDEX

FLEA SCREEN combo Spot On Dog

PRESENTATION

Spot on solution, light yellow to yellow clear liquid.

| | Small | Medium | Large | Extra Large |
|---------------------------------|-------|--------|-------|-------------|
| Weight (kg) | 2-10 | 10-20 | 20-40 | 40-60 |
| Volume of unit dose (ml) | 0.67 | 1.34 | 2.68 | 4.02 |
| Fipronil (mg) | 67 | 134 | 268 | 402 |
| S-methoprene (mg) | 60.3 | 120.6 | 241.2 | 361.8 |
| Butylhydroxyanisole (E320) (mg) | 0.134 | 0.27 | 0.54 | 0.8 |
| Butylhydroxytoluene (E321) (mg) | 0.067 | 0.13 | 0.27 | 0.4 |

USES

- To be used against infestations with fleas, alone or in association with ticks and/or biting lice.
- Treatment of flea infestations (*Ctenocephalides spp.*). Insecticidal efficacy against new infestations with adult fleas persists for 8 weeks. Prevention of the multiplication of fleas by inhibiting the development of eggs (ovicidal activity) and larvae and pupae (larvicidal activity) originating from eggs laid by adult fleas for eight weeks after application.
- Treatment of tick infestations (*Ixodes ricinus*, *Dermacentor variabilis*, *Dermacentor reticulatus*, *Rhipicephalus sanguineus*). The product has persistent acaricidal efficacy for up to 4 weeks against ticks.
- Treatment of infestations with biting lice (*Trichodectes canis*).

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.

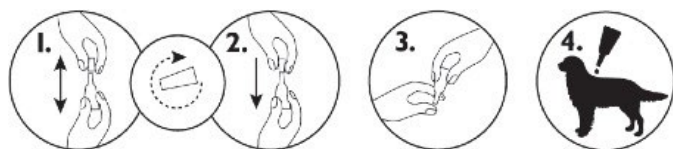
DOSE AND ADMINISTRATION

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

Dosage:

| Weight (kg) | Dosage |
|-------------|---------------------|
| 2-10 | 1 x 0.67 ml pipette |
| 10-20 | 1 x 1.34 ml pipette |
| 20-40 | 1 x 2.68 ml pipette |
| 40-60 | 1 x 4.02 ml pipette |

Administration: Remove the pipette from the triplex bag. Hold the pipette in an upright position, twist and pull the cap off. 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. Spread the animal hairs in the area between the shoulder blades to make the skin visible. Put the tip of the pipette onto the skin and press the unit-dose pipette several times to empty its contents directly onto the skin at one or two spots.



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.

The hair should be parted and the product applied to the skin. Temporary changes to the coat (clumped/greasy hair and/or deposits on the hair) may be noted at the application site.

Duration of treatment: For optimal control of flea and/or tick infestation the treatment schedule can be based on the local epidemiological situation.

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

USE DURING PREGNANCY AND LACTATION

Can be used during pregnancy and lactation.

CONTRA-INDICATION, WARNINGS, ETC

In the absence of available data, the product should not be used on puppies less than 8 weeks old and/or weighing less than 2 kg.

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.

This product is specifically developed for dogs. Do not use in cats and ferrets, as this could lead to overdosing.

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 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.

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

Among the very rare suspected adverse reactions, transient skin reactions on the application site (skin discoloration, 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), vomiting or respiratory symptoms have also been observed after use.

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.

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 container in order to protect from light and moisture. Do not remove from bag until required for use. The product should be maintained at room temperature (above 14°C) for approximately one hour prior to administration.

Shelf-life of the veterinary medicinal product as packaged for sale: 36 months.

FURTHER INFORMATION

Bathing/immersion in water within 2 days after application of the product and more frequent bathing than once a week should be avoided, as no study has been performed to investigate how this affects the efficacy of the product. Emollient shampoos can be used prior to treatment but reduce the duration of protection against fleas to approximately 5 weeks when used weekly after application of the product. Weekly bathing with a 2% chlorhexidine medicated shampoo did not affect efficacy against fleas during a 6 week long study.

There may be an attachment of a few ticks. For this reason a 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.

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 the treated animals with the immature stages of fleas.

LEGAL CATEGORY POM-V

PACKAGING

Presented in pipettes, individually wrapped in foil and cardboard boxes of 1 or 3 pipettes.

MARKETING AUTHORISATION NUMBER

| | |
|--|---------------|
| FLEA SCREEN combo Spot-On for Dogs – Small | Vm 01656/4125 |
| FLEA SCREEN combo Spot-On for Dogs – Medium | Vm 01656/4126 |
| FLEA SCREEN combo Spot-On for Dogs – Large | Vm 01656/4127 |
| FLEA SCREEN combo Spot-On for Dogs – Extra Large | Vm 01656/4128 |

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