

Prac-Tic Spot-On Solution for Dogs

Introduction



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Presentation

PRAC-TIC 56.25 mg spot-on solution for very small dogs
PRAC-TIC 137.5 mg spot-on solution for small dogs
PRAC-TIC 275 mg spot-on solution for medium dogs
PRAC-TIC 625 mg spot-on solution for large dogs
Each ml contains 125 mg pyriprole as a colourless to yellow, clear solution.

One pipette delivers:

| | Unit dose | Pyriprole |
|------------------------------|-----------|-----------|
| PRAC-TIC for very small dogs | 0.45 ml | 56.25 mg |
| PRAC-TIC for small dogs | 1.1 ml | 137.5 mg |
| PRAC-TIC for medium dogs | 2.2 ml | 275 mg |
| PRAC-TIC for large dogs | 5.0 ml | 625 mg |

Uses

Treatment and prevention of flea infestation (*Ctenocephalides canis* and *C. felis*) in dogs. Insecticidal efficacy duration against new infestations with fleas persists for a minimum of 4 weeks. The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).

Treatment and prevention of tick infestation (*Ixodes ricinus*, *Rhipicephalus sanguineus*, *Ixodes scapularis*, *Dermacentor reticulatus*, *Dermacentor variabilis*, *Amblyomma americanum*) in dogs. The veterinary medicinal product has persistent acaricidal efficacy duration of 4 weeks against ticks.

Dosage and administration

For spot-on use

The recommended minimum dose is 12.5 mg/kg bodyweight of pyriprole, equivalent to 0.1 ml/kg bodyweight of the veterinary medicinal product. Within each weight band the entire contents of the correct size pipette should be used.

| Weight of dog (kg) | Pipette size to be used | Volume of 12.5% (w/v) solution (ml) | Pyriprole (mg/kg bw) |
|--------------------|---|-------------------------------------|----------------------|
| 2 - 4.5 kg | Very small dog | 0.45 | 12.5 - 28.1 |
| >4.5 - 11 kg | Small dog | 1.1 | 12.5 - 30.6 |
| >11 - 22 kg | Medium dog | 2.2 | 12.5 - 25.0 |
| >22 - 50 kg | Large dog | 5.0 | 12.5 - 28.4 |
| >50 kg | Use the appropriate combination of pipettes | | |

Flea treatment and prevention

Pyriprole kills fleas within 24 hours post exposure. One application prevents flea infestation for 4 weeks. The veterinary medicinal product should be administered at monthly intervals when used as part of a treatment strategy for flea allergy dermatitis.

Tick treatment and prevention

Pyriprole kills ticks within 48 hours post-exposure. One application has acaricidal efficacy duration of 4 weeks.

Method of administration

For cutaneous use only.

Remove one pipette from the package. Hold it in an upright position. Tap the narrow part of the pipette to ensure the contents remain within the main body of it. Break the top of the snap-off top along the scored line.

Part the coat on the back of the animal between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze it gently several times at one or two spots to empty the contents onto the skin. Apply the 5 ml pipette to 2-3 spots

down the backline of large dogs in order to prevent run-off.

Care should be taken to avoid excessive wetting of the hair with the product since this will cause a clogged appearance of hair at the treatment spot. However, should this occur, it will disappear within 24 hours post application.

Contra-indications, warnings, etc

Do not use in dogs less than 8 weeks of age or with a body weight of less than 2 kg.

Do not use in case of known hypersensitivity to phenylpyrazole class compounds or any of the excipients.

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

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

Do not use on rabbits.

On very rare occasions the following have been reported:

- application site and skin reactions (pruritus, hair change, dermatitis, erythema, alopecia, fur discoloration and greasy appearance of hair).
- neurological reactions (ataxia and convulsions).
- systemic reactions (lethargy).
- digestive tract reactions (emesis and diarrhoea).

A brief period of hypersalivation may occur if the animal licks the application site immediately after treatment. This is not a sign of intoxication and disappears within minutes without treatment. Correct application will minimise licking of the application site.

As a precautionary measure, direct contact with the treated animals should be avoided and children should not be allowed to play with treated animals until the application site is dry. It is therefore recommended to treat animals in the evening. Recently treated animals should not be allowed to sleep in the same bed as their owners, especially children.

People with known hypersensitivity to the phenylpyrazole class compounds or any of the excipients should avoid contact with the veterinary medicinal product.

Avoid skin contact with the pipette content. Wash hands or other exposed body parts after use with soap and water. If accidental eye exposure occurs, the eyes should be rinsed carefully with water.

Do not smoke, eat or drink during application.

Apply only to the skin surface and on intact skin. This veterinary medicinal product is for spot-on application only. Do not administer orally or via any other route.

The dogs should be accurately weighed before the treatment. Care should be taken to avoid contact of the veterinary medicinal product with the eyes of the animal.

It is important to apply the dose to an area where the dog cannot lick it off and to make sure that animals do not lick each other following treatment.

Following treatment, ticks will detach from the host within 24 to 48 hours after infestation; however, single ticks might remain on the animal. For this reason, a transmission of infectious diseases by ticks cannot be completely excluded.

This veterinary medicinal product is for the treatment of ticks and adult fleas. All dogs in a household should be treated.

In cases of heavy infestation prior to treatment, the dog's surrounding should be vacuumed and treated with a suitable insecticide.

Dogs should not be bathed or shampooed from 48 hours before treatment. Immersion of the animal in water or shampooing within 24 hours after treatment may reduce the efficacy of the veterinary medicinal product. However, weekly immersion in water did not affect efficacy against fleas and ticks.

The safety of the veterinary medicinal product has not been established during pregnancy and lactation, nor in breeding animals, although in laboratory animal studies no indications of relevant effects on reproduction or foetal development were observed. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Prac-tic should not enter watercourses as this may be dangerous for fish and other aquatic organisms.

Pharmaceutical precautions

Keep out of the reach and sight of children

Store the pipettes in the original container in order to protect from light.

Do not store above 25°C.

Do not use after the expiry date stated on the pipette after "EXP".

Do not remove the pipette from the packaging until ready to use.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Legal category

POM-V

Packaging Quantities

Immediate packaging: The spot on pipette is composed of a bright yellow polypropylene shell, with a pale yellow aluminium foil back coated with a polyethylene terephthalate film. The pipette is contained in a child resistant soft tempered aluminium foil/PVC blister.

Outer packaging: Cardboard carton containing 1, 2 or 10 blisters each containing 3 pipettes.

Further information

Interaction with other medicinal products and other forms of interaction : None Known

The veterinary medicinal product is an insecticidal and acaricidal solution for spot-on use, containing pyriprole as active substance.

Pyriprole is an insecticide and acaricide belonging to the phenylpyrazole class. 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 fleas and ticks.

Parasites are killed through contact rather than by systemic exposure. Pyriprole kills fleas within 24 hours and ticks (*Ixodes ricinus*, *Rhipicephalus sanguineus*, *Dermacentor reticulatus*, *Ixodes scapularis*, *Dermacentor variabilis*, *Amblyomma americanum*) within 48 hours post-exposure.

Adult fleas are killed before they lay eggs for a minimum of 4 weeks after treatment. Since Prac-tic completely eliminates egg production, it breaks the flea life cycle.

Marketing authorisation number

PRAC-TIC-56.25mg-spot-on (3 pipettes)-EU/2/06/066/001.

PRAC-TIC-56.25mg-spot-on (6 pipettes)-EU/2/06/066/002.

PRAC-TIC-137.5mg-spot-on (3 pipettes)-EU/2/06/066/004.

PRAC-TIC-137.5mg-spot-on (6 pipettes)-EU/2/06/066/005.

PRAC-TIC-275mg-spot-on (3 pipettes)-EU/2/06/066/007.

PRAC-TIC-275mg-spot-on (6 pipettes)-EU/2/06/066/008.

PRAC-TIC-625mg-spot-on (3 pipettes)-EU/2/06/066/010.

PRAC-TIC-625mg-spot-on (6 pipettes)-EU/2/06/066/011.

Significant Changes