

Scalibor® Protectorband

anti-parasitic collar for dogs – 48 cm

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Marketing authorisation holder:

MSD Animal Health S.r.l.

Via Fratelli Cervi snc

Centro Direzionale Milano Due, Palazzo Canova

20090 Segrate, Milano, ITALY

Manufacturing authorisation holder responsible for batch release:

Intervet International B.V.

Wim de Körverstraat 35

5830AA Boxmeer, THE NETHERLANDS

OR

Intervet Productions S.A.

Rue de Lyons

27460 Igoville, FRANCE

NAME OF THE VETERINARY MEDICINAL PRODUCT

Scalibor® Protectorband 48 cm

anti-parasitic collar dogs.

STATEMENT OF THE ACTIVE SUBSTANCE

One white collar of 48 cm length contains:

Active substance:

Deltamethrin 0.760 g

Excipients:

Titanium dioxide (E171) 0.285 g

INDICATIONS

For dog ectoparasites sensitive to deltamethrin.

- prevention of infestations with ticks for 6 months;
- prevention of infestations with fleas for 4 months;
- repellent effect on adult mosquitoes (*Culex pipiens pipiens*) for 6 months.

Treatment provides a repellent effect against phlebotomine sandflies (*Phlebotomus perniciosus*) for 12 months.

The repellent (anti-feeding) effect of SCALIBOR on phlebotomine sandflies also reduces the risk of transmission of leishmaniasis in dogs.

Scalibor can therefore be considered as part of a programme for the prevention of infection by *Leishmania infantum*.

Since the product does not have a classic repellent action against ticks, it is possible to observe the presence of ticks even after the collar has been applied. Parasites die when exposed to the active ingredient present on the dog. The intake of toxic quantities leads to hyper-excitation followed by paralysis and death. As a result, ticks are unlikely to complete the blood meal.

CONTRAINDICATIONS

Do not use in dogs with known hypersensitivity to the active substance.

Do not use in puppies less than 7 weeks of age.

Do not use on cats.

Do not use on dogs with skin lesions.

ADVERSE REACTIONS

In rare cases, local skin reactions (pruritus, erythema, hair loss) involving the neck or the skin in general have been observed which might indicate a local or general hypersensitivity reaction.

Altered behaviour (e.g. lethargy or hyperactivity) often associated with skin irritation has been reported in very rare cases, too.

In very rare occasions, gastrointestinal symptoms such as vomiting, diarrhoea and hypersalivation have been observed.

In very rare cases, neuromuscular problems such as ataxia and muscle tremor have been observed. The symptoms usually subside within 48 hours after removal of the collar.

If any of these symptoms occur, the collar should be removed. Treatment should be symptomatic as no specific antidote is known.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

TARGET SPECIES

Dogs.

DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Use 1 collar per subject.

The collar should preferably be applied 1 week before the animals are introduced into an infested environment, as full activity is achieved after 1 week. It is recommended to treat all dogs in the same environment.

Bathing does not affect the efficacy of the collar. The collar can be used in puppies over 7 weeks of age.

ADVICE ON CORRECT ADMINISTRATION

Adjust the collar around the animal's neck without tightening too much. Cut off any excess length extending beyond 5 cm from the buckle.

WITHDRAWAL PERIOD

Not applicable.

SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.

SPECIAL WARNING(S)

Special precautions for use in animals:

In case of marked local irritation or allergic reactions, remove the collar immediately.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Wash hands with cold water and soap after applying the collar.

Do not allow children to play with the collar or put the collar in their mouths.

Avoid contact with eyes or mouth.

If the collar comes into contact with the eyes, rinse thoroughly with water.

People with known sensitivity to deltamethrin or to other components of the collar should avoid contact with the product.

If eye or skin irritation persists, or if the product is accidentally ingested, immediately contact your doctor showing him the package insert.

Treated dogs should not sleep in contact with people, especially with children.

Even if occasional contact with water does not reduce the efficacy of the collar, the collar should be removed before a bath or before a dog swim because the active ingredient is harmful to fish and other aquatic organisms. Dogs should not enter the water for the first 5 days after application of the collar.

Pregnancy and lactation:

No adverse reactions were observed in pregnant bitches to which the collar had been applied during the entire period of pregnancy and lactation. No symptoms were observed in puppies born from such bitches until weaning.

Overdose (symptoms, emergency procedures, antidotes):

In case of accidental ingestion of the collar by the dog, the following symptoms may be observed: incoordination of movements, tremors, hypersalivation. These symptoms are reversible within 48 hours. Treatment can only be symptomatic, as no specific antidotes are known.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS

Medicines should not be disposed of via wastewater or animal waste.

Ask your veterinarian how to dispose of medicines that you no longer need. These measures should help to protect the environment.

This veterinary medicinal product is dangerous for fish and other aquatic organisms. Do not contaminate lakes, streams or ditches with the product or its packaging.

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