

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Scalibor Protectorband 1.0 g medicated collar for large sized dogs
Scalibor vet 1.000 g medicated collar for dogs (Finland, Sweden)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One white collar of 65 cm length (25 g) contains:

Active substance:

Deltamethrin 1.000g

Excipient:

Titanium dioxide (E171) 0.375 g

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Medicated collar

White collar of smooth consistency with a plastic buckle at one extremity

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

Control of infestations with ticks (*Ixodes ricinus*; *Rhipicephalus sanguineus*) for 5 to 6 months.

Control of blood sucking by phlebotomine sandflies (*Phlebotomus perniciosus*) for a period of 5 to 6 months.

Anti-feeding effect on adult mosquitoes of the species *Culex pipiens pipiens* for 6 months.

4.3 Contraindications

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

Do not use on dogs with skin lesions.

Do not use in animals known to be hypersensitive to pyrethroids.

Do not use on cats.

4.4 Special warnings for each target species

As the collar exerts its full effect after one week, the collar should be preferably applied 1 week before animals are likely to become exposed to infestation.

In rare cases attachment of ticks can occur while wearing the collar. Under unfavourable conditions the transmission of infectious diseases through ticks or sandflies can therefore not be ruled out entirely.

4.5 Special precautions for use

Special precautions for use in animals

In case of skin lesions remove the collar until symptoms have resolved.

The influence of shampooing on the duration of efficacy has not been investigated.

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

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

People with known hypersensitivity to the ingredients of the collar should avoid contact with the veterinary medicinal product and the treated animal. Seek medical advice in case of hyper-sensitivity reactions.

Avoid letting children, in particular those under 2 years old, touch the collar, play with it or put it into their mouth.

Care should be taken not to allow young children to have prolonged intensive contact, e.g. sleeping with a pet wearing a collar.

Keep the sachet with the collar in the outer carton until use.

Other precautions

While occasional contact with water does not reduce the effectiveness of the collar, it should always be removed before swimming and bathing the dog because the active substance is harmful to fish and other aquatic organisms. Dogs must be prevented from swimming in water for the first five days of wearing the collar.

4.6 Adverse reactions (frequency and seriousness)

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

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

Gastrointestinal symptoms such as vomiting, diarrhoea and hypersalivation have been observed in very rare cases.

~~Neuromuscular~~ **Neurological** problems such as ataxia and muscle tremor have been observed in very rare cases. 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 treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Pregnancy:

Can be used during pregnancy.

Lactation:

Can be used during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use with other ectoparasiticides containing organophosphates.

4.9 Amounts to be administered and administration route

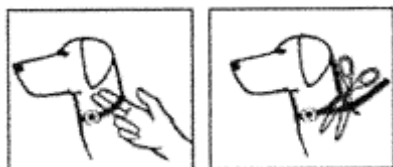
The 65cm long collar is to be used on large sized dogs.

For fastening around the neck.

One collar per dog.

For external use only.

Remove the collar from the sealed protective sachet. Adjust the collar around the animal's neck without tightening it too tight. Two fingers side-by side should fit between the band and the dog's neck. Slide the end through the buckle and cut off any excess length extending beyond 5 cm.



4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In the unlikely event of the dog eating the collar the following symptoms may occur: Uncoordinated movements, tremor, drooling of saliva, vomiting, rigidity of the hindquarters. These symptoms usually subside within 48 hours.

Diazepam can be used for symptomatic treatment if necessary.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: ectoparasiticides, insecticides and repellents, pyrethrins and pyrethroids

ATCvet code: QP53AC11.

5.1 Pharmacodynamic properties

Insects and acarines are exposed to deltamethrin through contact. The mechanism of action is based on a sustained increase in the sodium permeability of the insect's nerve membranes.

This results in hyperactivity followed by paralysis (shock effect), tremor and death of the parasite.

5.2 Pharmacokinetic particulars

Deltamethrin is continuously released from the collar into the coat and the fatty film covering the skin. The active substance spreads from the site of direct contact over the entire skin surface through the lipids and in the hair.

Deltamethrin is not absorbed systemically by the host.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Titanium Dioxide (E171)

Organo Ca-Zn Soap Blend

Epoxidized Soya Bean Oil

Diisooctyl Adipate

Triphenyl Phosphate

Polyvinyl Chloride

6.2 Major incompatibilities

None known.

6.3 Shelf life

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

6.4. Special precautions for storage

The collar sealed inside the foil sachet should be stored in the outer carton.
Store below 25 °C.

6.5 Nature and composition of immediate packaging

One collar is packed into a sachet made of paper-aluminium-polyethylene or paper-aluminium-polyester-polyethylene, and secured in the outer carton.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

Scalibor Protectorband should not enter water courses as this may be dangerous for fish and other aquatic organisms.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: {DD/MM/YYYY} {DD month YYYY}
Date of last renewal: {DD/MM/YYYY} {DD month YYYY}

10 DATE OF REVISION OF THE TEXT

{MM/YYYY} {DD/MM/YYYY} {DD month YYYY}

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.