

*[Version 9,03/2022]*

## **ANNEX I**

### **SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Scalibor Protectorband 0.760 g medicated collar for dogs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One white collar of 48 cm length contains:

### Active substance:

Deltamethrin 0.760 g

### Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Titanium dioxide (E171)	0.285 g
Organo Ca-Zn Soap Blend	
Epoxidized Soya Bean Oil	
Diisooctyl Adipate	
Triphenyl Phosphate	
Polyvinyl Chloride	

Medicated collar

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

## 3. CLINICAL INFORMATION

### 3.1 Target species

Dog

### 3.2 Indications for use for each target species

For the treatment and prevention of infestations with ticks (*Ixodes Ricinus*, *Rhipicephalus sanguineus*) for 6 months.

For the treatment and prevention of infestations with fleas (*Ctenocephalides felis*) for 4 months.

The veterinary medicinal product provides repellent (anti-feeding) efficacy against mosquitoes (*Culex pipiens pipiens*) for 6 months.

The veterinary medicinal product provides repellent (anti-feeding) efficacy against sand flies (*Phlebotomus perniciosus*) for 12 months.

By repelling the vector (*Phlebotomus perniciosus*), the veterinary medicinal product reduces the risk of transmission of the vector-borne pathogen *Leishmania infantum*. Therefore, the veterinary medicinal product can be considered as part of a program for the prevention of leishmaniosis infections in dogs.

The presence of single ticks after the application of the collar is possible, because the veterinary medicinal product has a limited repellent effect against ticks. The parasites will die when they are exposed to the active ingredient on the dog. Therefore, it is unusual for ticks to reach the stage of engorgement.

### 3.3 Contraindications

Do not use in dogs with known hypersensitivity to the active ingredient.  
 Do not use in puppies less than 7 weeks of age.  
 Do not use on cats.  
 Do not put the collar on an animal showing extensive cutaneous lesions.

### 3.4 Special warnings

The use of this product should take into account local information about susceptibility of the target parasites, where available.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal.

### 3.5 Special precautions for use

#### Special precautions for safe use in the target species:

In the case of marked local irritation or an obvious allergic reaction remove the collar immediately.

After treatment an attachment of single ticks and the feeding of single insect (fleas, sand flies, mosquitos) cannot be completely excluded. Therefore, transmission of infectious diseases (including *L. infantum*) cannot be completely excluded.

#### 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.

Do not allow children to either play or suck on the collar.

Avoid contact with eyes or mouth.

If collar comes into contact with eyes, flush eyes with water.

Person with a known sensitivity to deltamethrin or to one or more components of the collar should avoid contact with this product.

If skin or eye irritation persists, or if the product is accidentally swallowed, obtain medical attention immediately and show the package insert to the physician.

Treated dogs should not be allowed to sleep in contact with people, particularly children.

#### Special precautions for the protection of the environment:

While occasional contact with water does not reduce the effectiveness of the collar, it should always be removed before swimming and bathing the dog to avoid adverse effects on aquatic organisms. Dogs must be prevented from swimming in water for the first five days of wearing the collar.

### 3.6 Adverse events

Dogs

Rare (1 to 10 animals / 10,000 animals treated):	Localised skin reaction (pruritus/ scratching, erythema/ rash, hair loss) <sup>1</sup> Hypersensitivity reaction <sup>1</sup>
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Behavioural disorder (lethargy, hyperactivity) <sup>2</sup> Digestive tract disorders (vomiting, diarrhoea, hypersalivation) Neurological disorders (ataxia, muscle tremor) <sup>3</sup>

<sup>1</sup> involving the neck or the skin in general, which might indicate a local or general hypersensitivity reaction

<sup>2</sup> often associated with skin irritation

<sup>3</sup> subsides 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.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See also section 16 of the package leaflet for respective contact details.

### **3.7 Use during pregnancy, lactation or lay**

#### Pregnancy and lactation:

Can be used during pregnancy and lactation. No clinical side effect has been observed in bitches wearing the collar during the whole pregnancy and lactation period. No signs were observed in puppies from treated bitches up to weaning.

### **3.8 Interaction with other medicinal products and other forms of interaction**

Do not use with other ectoparasiticides containing organophosphates.

### **3.9 Administration routes and dosage**

External use.

1 collar per dog; adjust the collar around the animal's neck without tightening it.

Cut off excess collar 5 cm from the buckle.

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

It is recommended to treat all dogs in a household.

Baths do not affect the quality of the collar.

The collar can be put on puppies over 7 weeks.

### **3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**

In case of accidental ingestion of the collar by dog, the following symptoms could be observed: uncoordinated movements, tremors, hyper salivation. They are reversible in 48 hours. Treatment can be only symptomatically, as there is no specific antidote known.

### **3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

<To be completed in accordance with national requirements>

### **3.12 Withdrawal periods**

Not applicable.

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code:**

QP53AC11.

### **4.2 Pharmacodynamics**

Deltamethrin, the active ingredient of Scalibor collar, is a synthetic pyrethroid characterised by its acaricidal and insecticidal potency. Its mode of action is a modification of the sodium channels permeability resulting in hyperexcitation followed by paralysis (shock effect), tremor and mortality of the parasites.

#### **4.3 Pharmacokinetic**

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 dog. The cutaneous absorption of deltamethrin is negligible.

#### **Environmental properties**

Deltamethrin is harmful to fish and other aquatic organisms.

### **5. PHARMACEUTICAL PARTICULARS**

#### **5.1 Major incompatibilities**

None known.

#### **5.2 Shelf life**

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

#### **5.3 Special precautions for storage**

Store below 25 °C.

#### **5.4 Nature and composition of immediate packaging**

Cardboard box containing one collar in a sachet.

Sachet made of polyethylene-aluminium-kraft paper or polyethylene-polyester-aluminium-kraft paper.

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

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

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

### **6. NAME OF THE MARKETING AUTHORISATION HOLDER**

<To be completed locally>

### **7. MARKETING AUTHORISATION NUMBER(S)**

<To be completed locally>

**8. DATE OF FIRST AUTHORISATION**

26 April 1999

**9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

<{MM/YYYY}>

<{DD/MM/YYYY}>

<{DD month YYYY}>

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

The sale is not reserved to pharmacies and is not subject to medical prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**



**PARTICULARS TO APPEAR ON THE OUTER PACKAGE****Cardboard Box****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Scalibor Protectorband 0.760 g medicated collar

**2. STATEMENT OF ACTIVE SUBSTANCES**

Deltamethrin

0.760 g

**3. PACKAGE SIZE**

One collar

**4. TARGET SPECIES**

Dog

**5. INDICATIONS****For products not subject to veterinary prescription**For the treatment and prevention of infestations with ticks (*Ixodes Ricinus*, *Rhipicephalus sanguineus*) for 6 months.For the treatment and prevention of infestations with fleas (*Ctenocephalides felis*) for 4 months.The veterinary medicinal product provides repellent (anti-feeding) efficacy against mosquitoes (*Culex pipiens pipiens*) for 6 months.The veterinary medicinal product provides repellent (anti-feeding) efficacy against sand flies (*Phlebotomus perniciosus*) for 12 months.

By repelling the vector (*Phlebotomus perniciosus*), the veterinary medicinal product reduces the risk of transmission of the vector-borne pathogen *Leishmania infantum*. Therefore, the veterinary medicinal product can be considered as part of a program for the prevention of leishmaniosis infections in dogs.

**6. ROUTES OF ADMINISTRATION**

For external use.

**7. WITHDRAWAL PERIODS****8. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use immediately.

**9. SPECIAL STORAGE PRECAUTIONS**

Store below 25 °C.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

<to be completed locally>

**14. MARKETING AUTHORISATION NUMBERS**

<to be completed locally>

**15. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS****Sachet****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Scalibor Protectorband

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Deltamethrin                      0.760 g

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use immediately.

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Scalibor Protectorband 0.760 g medicated collar for dogs

### 2. Composition

One white collar of 48 cm length contains:

#### Active substance:

Deltamethrin	0.760 g
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#### Excipients:

Titanium dioxide (E171)	0.285 g
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### 3. Target species

Dog

### 4. Indications for use

For the treatment and prevention of infestations with ticks (*Ixodes Ricinus*, *Rhipicephalus sanguineus*) for 6 months.

For the treatment and prevention of infestations with fleas (*Ctenocephalides felis*) for 4 months.

The veterinary medicinal product provides repellent (anti-feeding) efficacy against mosquitoes (*Culex pipiens pipiens*) for 6 months.

The veterinary medicinal product provides repellent (anti-feeding) efficacy against sand flies (*Phlebotomus perniciosus*) for 12 months.

By repelling the vector (*Phlebotomus perniciosus*), the veterinary medicinal product reduces the risk of transmission of the vector-borne pathogen *Leishmania infantum*. Therefore, the veterinary medicinal product can be considered as part of a program for the prevention of leishmaniosis infections in dogs.

The presence of single ticks after the application of the collar is possible, because the veterinary medicinal product has a limited repellent effect against ticks. The parasites will die when they are exposed to the active ingredient on the dog. Therefore, it is unusual for ticks to reach the stage of engorgement.

### 5. Contraindications

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

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

Do not use on cats.

Do not put the collar on an animal showing extensive cutaneous lesions.

### 6. Special warnings

#### Special warnings:

The use of this product should take into account local information about susceptibility of the target parasites, where available.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal.

Special precautions for safe use in the target species:

In the case of marked local irritation or an obvious allergic reaction remove the collar immediately.

After treatment an attachment of single ticks and the feeding of single insect (fleas, sand flies, mosquitos) cannot be completely excluded. Therefore, transmission of infectious diseases (including *L. infantum*) cannot be completely excluded.

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.

Do not allow children to either play or suck on the collar.

Avoid contact with eyes or mouth.

If collar comes into contact with eyes, flush eyes with water.

Person with a known sensitivity to deltamethrin or to one or more components of the collar should avoid contact with this product.

If skin or eye irritation persists, or if the product is accidentally swallowed, obtain medical attention immediately and show the package insert to the physician.

Treated dogs should not be allowed to sleep in contact with people, particularly children.

Special precautions for the protection of the environment :

While occasional contact with water does not reduce the effectiveness of the collar, it should always be removed before swimming and bathing the dog to avoid adverse effects on aquatic organisms. Dogs must be prevented from swimming in water for the first five days of wearing the collar.

Pregnancy and lactation:

Can be used during pregnancy and lactation. No clinical side effect has been observed in bitches wearing the collar during the whole pregnancy and lactation period. No signs were observed in puppies from treated bitches up to weaning.

Interaction with other medicinal products and other forms of interaction:

Do not use with other ectoparasiticides containing organophosphates.

Overdose:

In case of accidental ingestion of the collar by dog, the following symptoms could be observed: uncoordinated movements, tremors, hyper salivation. They are reversible in 48 hours. Treatment can be only symptomatically, as there is no specific antidote known.

Major incompatibilities:

None known.

**7. Adverse events**

Dogs

Rare (1 to 10 animals / 10,000 animals treated):
Localised skin reaction (pruritus/ scratching, erythema/ rash, hair loss) <sup>1</sup>
Hypersensitivity reaction <sup>1</sup>
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Behavioural disorder (lethargy, hyperactivity) <sup>2</sup>
Digestive tract disorders (vomiting, diarrhoea, hypersalivation)
Neurological disorders (ataxia, muscle tremor) <sup>3</sup>

<sup>1</sup> involving the neck or the skin in general, which might indicate a local or general hypersensitivity reaction

<sup>2</sup> often associated with skin irritation

<sup>3</sup> subsides 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.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder<or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system.

## **8. Dosage for each species, routes and method of administration**

One collar per dog.

External use.

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

It is recommended to treat all dogs in a household.

Baths do not affect the quality of the collar.

The collar can be put on puppies over 7 weeks.

## **9. Advice on correct administration**

Adjust the collar around the animal's neck without tightening it.

Cut off excess collar 5 cm from the buckle.

## **10. Withdrawal periods**

Not applicable.

## **11. Special storage precautions**

Keep out of the sight and reach of children.

Store below 25°C.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and the carton after Exp. The expiry date refers to the last day of that month.

## **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater.

This veterinary medicinal product should not enter water courses as deltamethrin may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

## **13. Classification of veterinary medicinal products**

The sale is not reserved to pharmacies and is not subject to medical prescription.

## **14. Marketing authorisation numbers and pack sizes**

<To be completed locally>

**15. Date on which the package leaflet was last revised**

<{MM/YYYY}>

<{DD/MM/YYYY}>

<{DD month YYYY}>

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

**16. Contact details**

Marketing authorisation holder <and contact details to report suspected adverse reactions>:

<to be completed locally>

Manufacturer responsible for batch release:

Intervet International B.V.  
Wim de Korverstraat 35  
5831 AN Boxmeer  
Netherlands

or

Intervet Productions S.A.  
Rue de Lyons  
27460 Igoville  
France

<Local representatives < and contact details to report suspected adverse reactions>:>

<to be completed locally>

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below.>

<to be adjusted nationally>