[Version 9,03/2022]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Active substance:

Deltamethrin 1.0 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)	0.375 g
Organo Ca-Zn Soap Blend	
Epoxidized Soya Bean Oil	
Diisooctyl Adipate	
Triphenyl Phosphate	
Polyvinyl Chloride	

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

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each 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.

3.3 Contraindications

Do not use in puppies less than 7 weeks of age.
Do not use on dogs with skin lesions.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use on cats.

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the target species:
In case of skin lesions remove the collar until symptoms have resolved.

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 triphenyl phosphate should avoid contact with the veterinary medicinal product and the treated animal. Seek medical advice in case of hyper-sensitivity reactions.
This veterinary medicinal product contains deltamethrin which may cause transient tingling, itchiness and blotchy redness on exposed skin.
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.

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 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.

3.6 Adverse events

Dogs

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

[1] involving the neck or the skin in general, which might indicate a local or general hypersensitivity reaction
[2] often associated with skin irritation
[3] 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 “Contact details” of the package leaflet.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy.

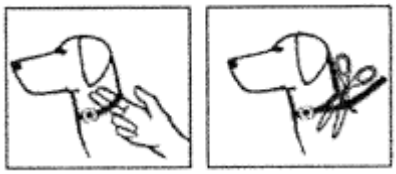
Lactation:
Can be used during lactation.

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

The 65cm long collar is to be used on large dogs.
For fastening around the neck.
One collar per dog.
For cutaneous use.
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.



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

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.

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

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP53AC11

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

Store below 25 °C.
Keep the foil sachet in the outer carton.

5.4 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.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

<To be completed nationally>

7. MARKETING AUTHORISATION NUMBER(S)

<To be completed nationally>

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: <{DD/MM/YYYY}> <{DD month YYYY}.>

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

IE: Veterinary medicinal product subject to prescription.
DE, AT, BE, CZ, DK, EE, FI, LT, LV, LU, NL, PL, SE, SK, (UK)NI: Veterinary medicinal product not subject to 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 1.0 g medicated collar for large dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Deltamethrin 1.0 g

3. PACKAGE SIZE

One collar

4. TARGET SPECIES

Dogs

5. INDICATIONS

For products not subject to veterinary prescription
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.

6. ROUTES OF ADMINISTRATION

For cutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

The collar sealed inside the foil sachet should be stored in the outer carton.
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 nationally}

14. MARKETING AUTHORISATION NUMBERS

{number}

15. BATCH NUMBER

Lot {number}

Do not use on cats.

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

1.0 g

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Scalibor Protectorband 1.0 g medicated collar for large dogs

2. Composition

Each white collar of 65 cm length contains:

Active substance:
Deltamethrin 1.0 g

Excipients:
Titanium dioxide (E171) 0.375 g

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

3. Target species

Dogs

4. Indications for use

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.

5. Contraindications

Do not use in puppies less than 7 weeks of age.
Do not use on dogs with skin lesions.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use on cats.

6. Special warnings

Special warnings:
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.

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

Special precautions for safe use in the target species:
In case of skin lesions remove the collar until symptoms have resolved.

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 triphenyl phosphate should avoid contact with the veterinary medicinal product and the treated animal. Seek medical advice in case of hyper-sensitivity reactions.
This veterinary medicinal product contains deltamethrin which may cause transient tingling, itchiness and blotchy redness on exposed skin.
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.

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 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.

Pregnancy:
Can be used during pregnancy.

Lactation:
Can be used during lactation.

Interaction with other medicinal products and other forms of interaction:
Do not use with other ectoparasiticides containing organophosphates.

Overdose:
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.

Major incompatibilities:
None known.

7. Adverse events

Dogs

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

[1] involving the neck or the skin in general, which might indicate a local or general hypersensitivity reaction
[2] often associated with skin irritation

[3] 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.

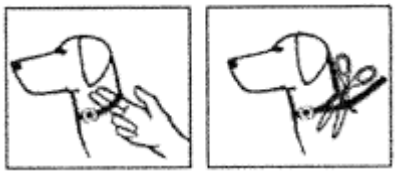
Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report 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

The 65cm long collar is to be used on large dogs.
For fastening around the neck.
One collar per dog.
For cutaneous use.

9. Advice on correct administration

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.



10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Store below 25 °C.
Keep the foil sachet in the outer carton.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and sachet 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 or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

IE: Veterinary medicinal product subject to prescription.
DE, AT, BE, CZ, DK, EE, FI, LT, LV, LU, NL, PL, SE, SK, (UK)NI: Veterinary medicinal product not subject to prescription.

14. Marketing authorisation numbers and pack sizes

< To be completed nationally>

Carton box with one collar packed into a sachet.

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 nationally>

Manufacturer responsible for batch release:

Intervet International B.V.
Wim de Körverstraat 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 nationally>