

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Scalibor Protectorband 0.76 g medicated collar for small and medium sized dogs
Deltamethrin

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:

Deltamethrin 0.760g

Excipients:

Titanium dioxide (E171)

3. PHARMACEUTICAL FORM

Medicated collar

4. PACKAGE SIZE

One collar

5. TARGET SPECIES

Dog

6. INDICATION(S)

For OTC products

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

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.

Do not use with other ectoparasiticides containing organophosphates.

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.

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.

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.

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.

While occasional contact with water does not reduce the effectiveness of the collar, it should 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.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

Store below 25 °C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4482

17. MANUFACTURER’S BATCH NUMBER

<Batch><Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Sachet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Scalibor 0.76 g medicated collar for small and medium sized dogs

Deltamethrin

2. QUANTITY OF THE ACTIVE SUBSTANCE

0.76 g

3. CONTENTS BY WEIGHT, VOLUME, OR BY NUMBERS OF DOSES

1 collar

4. ROUTE(S) OF ADMINISTRATION

External use

5. WITHDRAWAL PERIODS

6. BATCH NUMBER

<Batch> <Lot> {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Scalibor Protectorband 0.76 g medicated collar for small and medium sized dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands
or
Intervet Productions S.A.
Rue de Lyons
27460 Igoville
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Scalibor Protectorband 0.76 g medicated collar for small and medium sized dogs
Deltamethrin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

One white collar of 48 cm length contains:

Active substance:

Deltamethrin 0.760g

Excipients:

Titanium dioxide (E171) 0.285g

4. INDICATION(S)

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 animals known to be hypersensitive to pyrethroids.

Do not use on cats.



**DO NOT USE
ON CATS**

6. ADVERSE REACTIONS

Local skin reactions (e.g. pruritus/scratch, 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.

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).

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

7. TARGET SPECIES

Dog

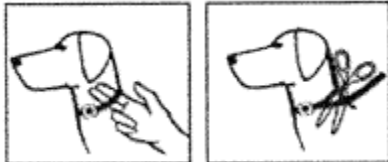
8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The 48cm long collar is to be used on small and medium sized dogs.
For fastening around the neck.

One collar per dog.
For external use only.

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 PERIOD(S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
The collar sealed inside the foil sachet should be stored in the outer carton.
Store below 25 °C.
Do not use after the expiry date which is stated on the carton and sachet.

12. SPECIAL WARNING(S)

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.

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.

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 (symptoms, emergency procedures, 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Do not contaminate ponds, waterways or ditches with the product or packaging as this may be dangerous for fish and other aquatic organisms.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

15. OTHER INFORMATION

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

Approved 01 October 2020

