

**IRISH MEDICINES BOARD ACT 1995**

**MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998**

**(S.I. No.142 of 1998)**

**10988/049/001**

Case No: 7002250

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

**Virbac Laboratories**

**1 ere Avenue - 2065 m, L.I.D., 06516 Carros Cedex, France**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

**Parasitex Insecticidal Collar**

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **15/12/2006** until .

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Parasitex Insecticidal Collar.

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Bendiocarb 10 % w/w

Excipients

Titanium dioxide 0.15 % w/w

For a full list of excipients see section 6.1.

#### 3 PHARMACEUTICAL FORM

Insecticidal collar.

#### 4 CLINICAL PARTICULARS

##### 4.1 Target Species

Dogs

##### 4.2 Indications for use, specifying the target species

For the control of flea and tick infestations on dogs.

##### 4.3 Contraindications

Do not use in animals known to be hypersensitive to the active substance.

This collar is suitable only for dogs. Do not use in other species.

Do not use on dogs which are sick or convalescing.

Do not use on dogs less than 8 months of age.

##### 4.4 Special warnings for each target species

None known.

## **4.5 Special precautions for use**

### **Special precautions for use in animals**

To be used for external treatment only.  
Do not allow the dog to chew the collar.

### **Special Precautions to be taken by the Person Administering the Product to Animals**

Do not open inner envelope until ready to use collar.  
Do not allow children to play with collar  
Do not bring hands in contact with eyes or mouth after handling the collar or touching the animal.  
Wash hands thoroughly after handling the collar or touching the animal.

## **4.6 Adverse reactions (frequency and seriousness)**

Some dogs may be sensitive to this collar. When collar is first fitted observe neck area daily for signs of irritation.  
Remove collar at the first signs of any adverse reaction.

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

In the absence of specific studies, it is recommended not to use Parasitex on pregnant or lactating bitches. Pregnant bitches may be treated if the benefit/risk ration is considered justified.

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

Do not use in conjunction with other insecticides as toxicity may be enhanced.

## **4.9 Amounts to be administered and administration route**

One collar only must be used on each dog. Fit collar securely - but not too tightly - around the dog's neck. Cut off any excess length and dispose of it in the recommended manner.

The collar becomes effective immediately and will kill fleas for up to 5 months. Remove and replace old collar after five months to ensure continued protection.

Check collar is not too tight to ensure against irritation.

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

Signs of toxicity include hypersalivation, gastrointestinal hypermotility, abdominal cramping, vomiting, diarrhoea, sweating, dyspnoea, cyanosis, miosis, muscle fasciculations.

Treatment: treatment of carbamate poisoning is similar to that of organophosphates in that atropine sulphate injections readily reverse the effects of cholinesterase inhibition. Recommended dosage is as follows:

Dogs: dosed to effect (repeated as needed): usually 0.2 mg/kg parenterally (1/4 of the dose given intravenous and the remainder given subcutaneous).

## **4.11 Withdrawal Period(s)**

Not applicable.

## **5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

PARASITEX insecticidal collar for dogs contains bendiocarb as active ingredient.

Bendiocarb is a broad spectrum insecticide of the carbamate family which acts by inhibiting parasite cholinesterases.

When fitted around the dog's neck, bendiocarb will begin continuous release from the collar and for a period of 5 months, providing protection against flea and tick infestations

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Di (2-ethyl hexyl) adipate

Epoxidised soya oil

Calcium Stearate

Titanium Dioxide

Polyvinyl Chloride

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf-life**

2 years.

### **6.4 Special precautions for storage**

Keep out of the reach of children.

Do not remove the collar from the pack until ready to use.

Do not store above 25°C.

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

One collar 65 cm/35 g in a container of white kraft paper/polyethylene/aluminium/polyethylene laminated sachet heat sealed.

### **6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials**

Any unused product or waste material should be disposed of in accordance with national requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Virbac S.A.,

1 ère Avenue 2065 M – L.I.D.,

06516 Carros,

France.

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10988/49/1

**9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

12<sup>th</sup> August 1998