# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Clear Wormer 500 mg Film Coated Tablets for Dogs

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

| **Active substance;** | **Quantity:** | |
|---|---|---|
| Nitroscanate | 500 | mg |

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated Tablet.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Dogs.

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

The product is a broad spectrum anthelmintic for use in puppies and adult dogs for the treatment of infection by adult intestinal nematodes or cestodes of the following species:
Nematodes: *Toxocara caninum, Toxascaris leonina, Ancylostoma caninum, Uncinaria stenocephala*
Cestodes: *Taenia hydatigena, Taenia pisiformis*, and *Dipylidium caninum*.

### 4.3 Contraindications

Do not administer to sick or convalescing animals. Do not use in puppies of less than 3 weeks of age. Do not use in cases of hepatic dysfunction. Do not use in cases of known hypersensitivity to the active substance.

### 4.4 Special warnings for each target species

The product is not indicated for the treatment of *Trichuris vulpis* and gives only a limited level of control of *Echinococcus granulosus.*
Since the most common tapeworm of the dog (*Dipylidium caninum*) is transmitted by a flea and has a very short pre-patent period, it is important to pay attention to flea control to reduce the incidence of tapeworm in your pet.

## 4.5 Special precautions for use

**Special precautions for use in animals:**

Do not repeat treatment if vomiting occurs shortly after dosing.
Administer with food (See 4.9)

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

Wash hands after use.

## 4.6 Adverse reactions (frequency and seriousness)

When the product is not administered as recommended occasionally vomiting may occur.

## 4.7 Use during pregnancy, lactation or lay

The product can be used during pregnancy and lactation.

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

None known.

## 4.9 Amounts to be administered and administration route

For oral administration.
The dose is 50 mg nitroscanate per kg bodyweight, which is equivalent to 1 x 500 mg tablet per 10 kg bodyweight.
Tablets should not be broken before administration.
The dosing programme should be established by the veterinary surgeon.

The product should be administered orally in the morning after overnight fasting with approximately one-fifth of the daily food ration. The remaining food ration should be withheld for at least 8 hours.

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

In studies using up to nine times the recommended dose of nitroscanate dogs showed no clinical symptoms. However, increased levels of serum enzymes ALT and ALP suggestive of liver dyscrasia were observed in some of the dogs receiving 3 (for ALT) or 5 (for ALT and ALP) times the recommended dose.

## 4.11 Withdrawal Period(s)

Not applicable.

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Active Substance: Nitroscanate
Pharmacotherapeutic group: Anthelmintic.
ATCvet-code: QP52AX01

### 5.1 Pharmacodynamic properties

Nitroscanate is an anthelmintic of the diphenyloxide group. Nitroscanate is known to interfere with and inhibit the synthesis of ATP in *Fasciola hepatica* while A.M.P. levels are increased. The alterations in A.T.P. levels are shown to be irreversible and continuous with time. Neither interference in the uptake of glucose nor the mobilisation of glycogen are observed. An initial increase in end-product formation, namely acetate and lactate is observed, possibly due to increased levels of the enzyme phosphofructokinase resulting from depletion of A.T.P. levels, but this increase is later abolished.

In the nematode *Haemonchus contortus* adenine nucleotide pools are depressed by nitroscanate.

Efficacy of nitroscanate is increased approximately four-fold if given with food due to slower passage of the drug through the gastrointestinal tract, with increased contact time with the parasite.

### 5.2 Pharmacokinetic properties

When administered orally, the drug is only partly absorbed from the gastrointestinal tract, with the majority of the dose being eliminated in the faeces. The remainder of the dose is metabolised and excreted in the urine. The principal urinary metabolite is 4-(4-aminophenoxy) acetanilide. The concentration of nitroscanate in contact with the helminths in the gastrointestinal tract and the absorption into the fatty layers of these helminths is probably more important for the purpose of efficacy than absorption into the blood.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Maize Starch Ph. Eur.
Microcrystalline Cellulose (E460) Ph. Eur.
Sodium Starch Glycolate Type A Ph. Eur.
Sodium Lauryl sulfate Ph. Eur.
Magnesium Stearate (E572) Ph. Eur.
HPMC 2910
Polydextrose FCC
Polyethylence glycol 4000
*Opadry GM 7900 (film coating)

* Includes Titanium Dioxide (E171), Iron Oxide Yellow (E172), Iron Oxide Black (E172) and Iron Oxide Red (E172).

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.

## 6.4 Special precautions for storage

Store in a dry place.
Do not store above 25°C.

## 6.5 Nature and composition of immediate packaging

Aluminium foil strips in outer carton.
2 x 500 mg Nitroscanate tablet pack.
3 x 500 mg Nitroscanate tablet pack.
4 x 500 mg Nitroscanate tablet pack.

Not all pack sizes may be marketed.

## 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

Bob Martin (UK) Ltd.,
Wemberham Lane
Yatton
Somerset BS19 4BS
England.

## 8 MARKETING AUTHORISATION NUMBER(S)

VPA 10881/002/001

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

Date of first authorisation 10th July 1995

Date of last renewal 9th July 2010

## 10 DATE OF REVISION OF THE TEXT

February 2015