

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Harkers Carnidazole Tablets 10 mg

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

#### Qualitative composition

#### Quantitative composition

Active ingredient:

Carnidazole

10 mg per tablet

For a full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Tablet.

Round white uncoated tablet with one side scored "Janssen".

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Pigeons

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

Therapeutic and routine treatment of trichomoniasis (canker) in pigeons caused by *Trichomonas columbae*.

#### **4.3 Contraindications**

None

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

None

#### **4.5 Special precautions for use**

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

All birds in the loft should preferably be treated before feeding. At the time of treatment no drinking troughs should be present until 2 hours after treatment when they can be returned to the loft after being thoroughly disinfected. Repeat the treatment when the possibility of re-infection is high, at the start of the reproductive period, at the beginning of brooding, when bringing in new birds, etc.

- ii. Special precautions for the person administering the veterinary medicinal product to animals

Direct contact with the product must be avoided. Wear impermeable gloves when handling the product.

Do not use the product if you are allergic to ingredients in the product.

Wash hands immediately after using the product.

If after handling the product irritation develops, wash the affected area thoroughly with water. If irritation persists, seek medical attention.

Do not touch eyes whilst handling the product. In case of accidental eye contact, wash the eyes thoroughly with water. Seek medical attention if irritation persists.

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

None known

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

Harkers Carnidazole Tablets 10 mg are safe for use in breeding birds with and without young.

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

None known

#### **4.9 Amount(s) to be administered and administration route**

##### Posology

20 mg/kg body mass.

One tablet orally per adult pigeon; ½ tablet orally for young weaned pigeons.

##### Method of administration

The tablet is placed directly into the mouth. All pigeons in the loft should be treated simultaneously to prevent untreated birds acting as a source of re-infection for the treated birds.

Routine treatment:

Young pigeons: - at weaning

Adult pigeons: - before mating  
- during the first part of the brooding period  
- after return from races when the birds have been in the travel boxes for a long time.

Therapeutic treatment: when *Trichomonas* infection has been diagnosed.

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

Overdosing has not been seen to cause any symptoms, even after 32 times the recommended therapeutic dose. At these high dosage rates vomiting can occur in a few pigeons 3 to 6 hours after dosing.

#### **4.11 Withdrawal period(s)**

Harkers Carnidazole Tablets 10 mg must not be used in pigeons intended for human consumption.

### **5. PHARMACOLOGICAL PROPERTIES**

**Pharmacotherapeutic group:** Agents against protozoal diseases

**ATC Vet Code:** QP51AA09

Carnidazole is a trichomonacide belonging to the 5-nitro-imidazole group.

#### **5.1 Pharmacodynamic properties**

Nitroimidazoles are thought to interact with the parasite's DNA, thereby destroying its ability to act as a template for protein synthesis.

#### **5.2 Pharmacokinetic properties**

Not known

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Lactose monohydrate  
Cellulose microcrystalline  
Silica colloidal anhydrous  
Sodium lauryl sulphate  
Magnesium stearate

#### **6.2 Incompatibilities**

None known

#### **6.3 Shelf life**

Shelf life of veterinary medicinal product as packaged for sale: 4 years.

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

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

**6.5 Nature and composition of immediate packaging**

Two green polyvinyl chloride/aluminium blister packs containing 25 tablets each, in an outer carton (50 tablets per box).

**6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

**7. MARKETING AUTHORISATION HOLDER**

Harkers Limited  
Unit 2, Cavendish Road  
Bury St Edmunds  
Suffolk  
IP33 3TE

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

**Vm** 11245/4002

**9. DATE OF FIRST AUTHORISATION**

**Date:** 15 September 1992

**10. DATE OF REVISION OF THE TEXT**

**Date:** June 2013

APPROVED *T. NASH* 14/06/13