PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Harkers Carnidazole 10 mg Tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Carnidazole 10 mg

3. PHARMACEUTICAL FORM

Tablet.

4. PACKAGE SIZE

50 tablets

5. ARGET SPECIES

Pigeons

6. INDICATION(S)

For oral treatment of canker (trichomoniasis) in pigeons.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

20 mg/kg body mass.

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

Read package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

User Warnings
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.

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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.

10. EXPIRY DATE

EXP: End {month/year}

11. SPECIAL STORAGE CONDITIONS

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

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

Dispose of empty packaging and any remaining product in the household refuse.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

AVM-GSL

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 11245/4002

17. MANUFACTURER'S BATCH NUMBER

Batch no.

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MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Harkers Carnidazole 10 mg Tablets

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Harkers Limited

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Batch no.

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

ADDITIONAL INFORMATION

For oral administration

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PACKAGE LEAFLET FOR: Harkers Carnidazole 10 mg Tablets

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

Marketing authorisation holder : Harkers Limited, Unit 2, Cavendish Road Bury St Edmunds, Suffolk, IP33 3TE

Manufacturer for batch release: Janssen Pharmaceutica, Beerse, Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Harkers Carnidazole 10 mg Tablets

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

Each tablet contains 10 mg carnidazole as active substance.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

None known.

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

7. TARGET SPECIES

Pigeons

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

20 mg/kg body mass.

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

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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.

9. ADVICE ON CORRECT 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.

10. WITHDRAWAL PERIOD(S)

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Do not store above 25ºC.
Protect from light.
Store in a dry place.

12. SPECIAL WARNING(S)

For Animal Treatment Only

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.

User Warnings

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.

Adverse reactions: None known

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

Interaction with other medicinal products and other forms of interaction: None known.

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

Dispose of empty packaging and any remaining product in the household refuse.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

tba

15. OTHER INFORMATION

Carnidazole is a trichomonacide belonging to the 5-nitro-imidazole group. Nitroimidazoles are thought to interact with the parasite's DNA, thereby destroying its ability to act as a template for protein synthesis.

Pack size: carton containing 50 tablets

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Vm 11245/4002

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