

SUMMARY OF PRODUCT CHARACTERISTICS

1. 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Harkers Pigeon Coccidiosis Treatment 3.84% w/v Concentrate for Oral Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active ingredient</u>	<u>% w/v</u>
Amprolium hydrochloride	3.84
<u>Excipients:</u>	
<u>Preservatives:</u>	
Methyl parahydroxybenzoate	0.20% w/v
Propyl parahydroxybenzoate	0.02% w/v
<u>Colouring agents:</u>	
Patent Blue V (E131)	0.0005% w/v
Quinoline Yellow (E104)	0.000625% w/v

3. PHARMACEUTICAL FORM

Concentrate for oral solution.
A green solution.

4. CLINICAL PARTICULARS

4.1 Target species

The product is indicated for use in pigeons (*Columbidae*).

4.2 Indications for use, specifying the target species

For the treatment of coccidiosis in pigeons.

4.3 Contraindications

This coccidiostat must not be mixed or used simultaneously with any other medicinal product or substance having a similar effect.

4.4 Special warnings for each target species

Not applicable.

4.5 Special precautions for use

Special precautions for use in animals

There are no special precautions associated with use of this product.

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

In case of accidental spillage on to the skin or eyes, wash the affected area with clean running water immediately. Seek medical attention if irritation persists.

4.6 Adverse reactions (frequency and seriousness)

There have been no undesirable effects observed in the target species following recommended use of this product.

4.7 Use during pregnancy, lactation or lay

As the product is indicated for use only in birds, there is no information applicable to this product.

4.8 Interaction with other medicinal products and other forms of interaction

No studies have been conducted on interactions between this and any other medicinal product.

4.9 Amounts to be administered and administration route

For oral use only.

To be added to the drinking water at a rate of 28ml per 4.5 litres (1fl oz per gallon) for 7 days. In serious outbreaks of coccidiosis, treatment at half strength (14ml per 4.5 litres) should be continued for a further 7 days. The birds should not have access to unmedicated drinking water during the period of treatment.

112ml is sufficient to treat about 30 birds and 500ml is sufficient to treat about 130 birds.

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

Not applicable.

4.11 Withdrawal period(s)

Do not use in pigeons intended for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiparasitic products, insecticides and repellants

ATCvet code: QP51 AX09

5.1. Pharmacodynamic properties

Amprolium hydrochloride is a coccidiostatic agent whose action depends on the fact that it is antagonistic to thiamine. It is considered that amprolium by antagonising thiamine denies thiamine to the coccidian and since the requirements of coccidian for thiamine are greater than those of the host, the coccidian suffer more from this deprivation.

5.2 Pharmacokinetic particulars

No data presented.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl hydroxybenzoate
Propyl hydroxybenzoate
Patent Blue V (E131)
Quinoline yellow (E104)
Sodium citrate dihydrate
Citric acid anhydrous
Water purified

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of veterinary medicinal product as packaged for sale: 2 years
Shelf-life after dilution or reconstitution according to directions: 24 hours

6.4 Special precautions for storage

Do not store above 25°C.

Protect from light.

Any medicated water which is not consumed within 24 hours should be discarded.

6.5 Nature and composition of immediate packaging

A.	Size:	112ml
	Container:	High-density polyethylene bottle
	Closures:	Polypropylene cap (screw fit)
	Dosing devices:	Not applicable
B.	Size:	500ml
	Container:	High-density polyethylene dispenser bottle, twin necked with 25ml conical dispensing chamber
	Closures:	Urea formaldehyde cap (screw fit)
	Dosing devices:	Dispensing chamber

Not all pack sizes may be marketed.

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

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 11245/4003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th April 1996

10. DATE OF REVISION OF THE TEXT

29 August 2008