SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Appertex 2.5mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient

Clazuril 2.5mg per tablet

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.
White circular bioconvex tablet inscribed Janssen and Appertex on opposing faces.

4. CLINICAL PARTICULARS

4.1 Target species

Pigeons

4.2 Indications for use, specifying the target species

Therapeutic and routine treatment of coccidiosis in homing pigeons caused by:
Eimeria labbeana
Eimeria columbarum

4.3 Contraindications

None known

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

The product is not soluble in water and cannot be administered in the drinking water. Do not use simultaneously with L-Spartakon as the latter drug may cause vomiting.

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

Wash hands after administration of the tablets to birds and after clearing the waste from treated birds.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Can be used safely during reproduction and holds no danger for young pigeons still in the nest.

4.8 Interaction with other medicinal products and other forms of interaction

Should not be administered simultaneously with other drugs.

4.9 Amounts to be administered and administration route

For oral administration only; 5 mg/kg body mass, equivalent to 1 tablet per pigeon

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

Routine treatment:
Breeding pigeons should be treated before mating and again three weeks later. Good management and hygiene in the lofts is essential for the prevention of re-infection.

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

At overdosing of up to 128 times the recommended therapeutic dose the only symptoms seen were vomiting and loose faeces. These symptoms were mild and transitory in nature. No specific treatment was necessary. Deaths were never seen.

4.11 Withdrawal period(s)

Appertex must not be used in pigeons intended for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Agents against protozoal diseases

ATCvet code: QP51 AJ02

Clazuril is an anticoccidial belonging to the group of the benzene-acetonitriles.

5.1. Pharmacodynamic properties

Clazuril has its anticoccidial effect by means of a cidal effect on the endogenous stages of the Eimeria species in pigeons.

5.2 Pharmacokinetic particulars

Clazuril is rapidly absorbed with maximum plasma concentrations found 5 – 8 hours after dosing. The half-life of clazuril in pigeons is about 3 days.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize starch
Cellulose microcrystalline
Pregelatinised starch
Povidone K90
Magnesium stearate
Silica colloidal anhydrous
Polysorbate 20

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

30 tablets in polyvinylchloride blister pack with an aluminium foil closure in an outer carton.

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.
Excreta from treated birds should not be spread onto land used for growing crops.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

Vm 11245/4000

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17 September 1992

10 DATE OF REVISION OF THE TEXT

August 2008