

PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Appertex 2.5 mg Tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Clazuril 2.5 mg

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

5. TARGET SPECIES

Homing and show pigeons

6. INDICATION(S)

For the oral treatment and control of Coccidiosis caused by *Eimeria labbeana* & *Eimeria columbarum* in homing and show pigeons

7. METHOD AND ROUTE(S) OF ADMINISTRATION

One tablet per pigeon regardless of weight. To be placed into mouth.

If signs of disease persist or appear, consult a veterinary surgeon.

8. WITHDRAWAL PERIOD

Not for use in pigeons intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Do not administer with drugs that may cause vomiting. Birds should be treated when mated and again 3-4 weeks later to prevent infection of nestlings. Birds should be treated following transportation to shows or races where they may be exposed to contaminated cages, baskets etc. Wash hands after administration of the tablets to birds and after cleaning the waste from treated birds.

If signs of disease persist or appear, consult a veterinary surgeon.

For use in pigeons only.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Store in a dry place.

Keep the container in the outer carton.

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

See pack leaflet

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [*Distribution category*]

For animal treatment only

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| AVM- GSL |
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14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH 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 11245/4000

17. MANUFACTURER’S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Appertex 2.5 mg Tablets

Clazuril 2.5 mg

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Harkers

3. EXPIRY DATE

4. BATCH NUMBER

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

Keep container in outer carton

PACKAGE LEAFLET FOR:

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Appertex 2.5mg Tablets

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

Presentation: round white tablets containing 2.5 mg clazuril

4. INDICATION(S)

For the oral treatment and control of Coccidiosis caused by *Eimeria labbeana* & *Eimeria columbarum* in homing and show pigeons

5. CONTRAINDICATIONS

Do not administer with drugs that may cause vomiting.

6. ADVERSE REACTIONS

7. TARGET SPECIES

Homing and show pigeons

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

One tablet per pigeon regardless of weight. Administer into mouth. All birds in the same loft should be treated simultaneously to prevent re-infection.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Not for use in pigeons intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Store in a dry place.

Keep the container in the outer carton.

Keep out of the reach and sight of children

12. SPECIAL WARNING(S)

Birds should be treated when mated and again 3-4 weeks later to prevent infection of nestlings. Birds should be treated following transportation to shows or races where they may be exposed to contaminated cages, baskets etc. Wash hands after administration of the tablets to birds and after cleaning the waste from treated birds.

For Animal Treatment Only

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

AVM - GSL

Vm 11245/4000

Appertex can safely be administered to pigeons during the breeding season, it has no adverse effects on the condition of the nestlings. In order to reduce the risk of re-infection following treatment, good management and hygiene practices are essential, in particular the regular cleaning of the premises to remove pigeon excreta.

If signs of disease persist or appear, consult a veterinary surgeon.

Approved: 08/01/2018

