ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MERANOX 25 mg/ml oral suspension for pigeons
Fenbendazole

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Fenbendazole	25 mg/ml
Benzyl alcohol (E1519)	20 mg
Azorubine 85% (E122)	12 µg

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

10 ml
30 ml
50 ml

5. TARGET SPECIES

Pigeons

6. INDICATION(S)

Treatment of the following gastro-intestinal nematodes in pigeons:

- Ascaridia spp. (adult stages)
- Capillaria spp. (adult stages)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Do not use in pigeons producing food for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 28 days.
Once opened, use by_____.

11. SPECIAL STORAGE CONDITIONS

Keep the bottle tightly closed.
Keep the bottle in the outer carton in order to protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS ORWASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS ORRESTRICTIONS REGARDING SUPPLY AND USE, IF

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Avimedical B.V.

Abbinkdijk 1
7255 LX Hengelo (Gld)
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 43564/4002

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MERANOX 25 mg/ml oral suspension for pigeons
Fenbendazol

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Fenbendazole 25 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml
30 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

For oral use.

5. WITHDRAWAL PERIOD

Do not use in pigeons producing food for human consumption.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP{month/year}
Shelf life after first opening the immediate packaging: 28 days.
Once opened, use by_____.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
MERANOX 25 mg/ml oral suspension for pigeons

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

Marketing authorisation holder:

Avimedical B.V.

Abbinkdijk 1
7255 LX Hengelo (Gld)
The Netherlands

Manufacturer responsible for batch release:

Floris Veterinaire Producten B.V.
Kempenlandstraat 33
5262 GK Vught
THE NETHERLANDS

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

MERANOX 25 mg/ml oral suspension for pigeons

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

Active substance:

Fenbendazole	25 mg/ml

Excipient(s)

Benzyl alcohol (E-1519)	20 mg/ml
Azorubine 85% (E122)	12 µg/ml

Description:

Slightly pink viscous suspension.

4. INDICATION(S)

Treatment of the following gastro-intestinal nematodes in Pigeons:

- Ascaridia spp., i.e. roundworms (adult stages)
- Capillaria spp., i.e. hairworms (adult stages)

5. CONTRAINDICATIONS

Birds should not be treated with fenbendazole during moulting.

6. ADVERSE REACTIONS

No adverse reactions have been detected when the product is administered at the recommended dose. Please refer to section 12 for information regarding overdose. If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigeons.

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

For oral use.

The dose is 25 mg/kg bodyweight per day (0.1 ml/100 g bodyweight). This dose should be administered twice at a time interval of 14 days.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure administration of the correct dose, body weight should be determined as accurately as possible.

In order to ensure that the correct dose is administered safely, administration using a crop needle is preferable, which should be performed by an appropriately trained person. Where this is not practicable, the product should be administered in the beak.

It is not necessary to restrict food during treatment.

To avoid inhalation of the medication, care should be taken with restraint of the animal and administration of the product.

All the animals belonging to the same group should be treated at the same time.

After use the syringes should be washed with lukewarm water to remove any remaining product.

10. WITHDRAWAL PERIOD

Do not use in pigeons producing food for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the bottle tightly closed.
Keep the bottle in the outer carton in order to protect from light.
Do not use after the expiry date stated on the label and carton after EXP
Shelf life after first opening the immediate packaging: 28 days.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

Parasitic resistance to any particular class of anthelmintic may develop following frequent repeated use of an anthelmintic of that class.

In order to prevent reinfestation of the treated animals, it is important to carry out environmental control measures, such as disinfection of the enclosure and food/water bowls, and disposal of substrate/bedding, in order to destroy or remove any eggs in the environment.

Use of the product deviating from the instructions in the SPC may increase the risk of development of resistance.

Safety of the product has not been investigated in immature birds. Use only according to the benefit/risk assessment by the responsible veterinarian.

Safety and efficacy trials of the product were conducted in the domestic pigeon (Columba livia). Use in other species of pigeon should be according to a benefit:risk assessment by the responsible veterinarian.

Product administration on consecutive days may lead to severe toxic effects.

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

This product may be toxic to humans after ingestion.

This product may cause hypersensitivity (allergy) reactions.

People with known hypersensitivity to fenbendazole should avoid contact with the veterinary medicinal product.

Avoid contact with skin, eyes and mucous membranes.

In case or skin and/or eye contact, immediately rinse with plenty or clean water. Due to the risk or accidental ingestion, never leave a loaded syringe unattended.
In case or accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

Pregnancy, lactation and lay:

The safety of the veterinary medicinal product has not been established during lay. Use only accordingto the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Exacerbation of paracetamol hepatotoxicity by fenbendazole cannot be excluded.

Overdose (symptoms, emergency procedures, antidotes):

Overdoses can result in a decrease in white blood cells (leukopaenia, including heteropaenia), anaemia,intestinal crypt cell degradation, bone marrow suppression, immunosuppression and death.
Bloodchemistry parameters gamma GT and CPK can increase. Vomiting after administration can occur.

Treatment is symptomatic.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with otherveterinary medicinal products.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2022

15. OTHER INFORMATION

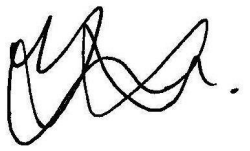
Pharmacotherapeutic group: Anthelmintics, benzimidazole derivatives – fenbendazole.ATCvet code: QP52AC13.

Package (size)

Cardboard box containing (an) amber glass (type III) bottle(s) with a tamper-evident HDPE screw caps with ring and colourless LDPE syringe insert. Graduated oral syringe(s) is (are) also included. Cardboard box containing 10 separate boxes, each containing 1 bottle.

1 x 10 ml, 10 x 10 ml.

1 x 30 ml, 10 x 30 ml.
1 x 50 ml, 10 x 50 ml.
Not all pack sizes may be marketed.



Approved: 29 June 2022