# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MERANOX 25 mg/ml oral suspension for pigeons

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per ml:

**Active substance:**

| | |
|---|---|
| Fenbendazole | 25 mg |

**Excipients:**

| | |
|---|---|
| Benzyl alcohol (E1519) | 20 mg |
| Azorubine 85% (E122) | 12 µg |

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Oral suspension
Slightly pink suspension

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Pigeons

### 4.2 Indications for use, specifying the target species

Treatment of the following gastro-intestinal nematodes in pigeons:

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

### 4.3 Contraindications

Birds should not be treated with fenbendazole during moulting.

## 4.4 Special warnings for each target species

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.

## 4.5 Special precautions for use

Special precautions for use in animals

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 pigeons. 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.

## 4.6 Adverse reactions (frequency and seriousness)

No adverse reactions have been detected when the product is administered at the recommended dose. Please refer to section 4.10 for information regarding overdose.

## 4.7 Use during pregnancy, lactation or lay

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

## 4.8 Interaction with other medicinal products and other forms of interaction

Exacerbation of paracetamol hepatotoxicity by fenbendazole cannot be excluded.

## 4.9 Amounts to be administered and administration route

For oral use.

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

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

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.

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

After use, wash the syringe in warm water and allow to dry.

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

Overdoses in birds can result in a decrease in white blood cells (leukopaenia, including heteropaenia), anaemia, intestinal crypt cell degradation, bone marrow suppression, immunosuppression and death.

Blood chemistry parameters gamma GT and CPK can increase.
Vomiting after administration can occur.

Treatment is symptomatic.

## 4.11 Withdrawal period(s)

Do not use in pigeons producing food for human consumption.

## 5. PHARMACOLOGICAL PROPERTIES

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

### 5.1 Pharmacodynamic properties

Fenbendazole is an anthelmintic belonging to the benzimidazole-carbamate group. It acts byinterfering with the energy metabolism of the nematode.

Fenbendazole inhibits the polymerisation of tubulin to microtubules. This interferes with essential structural and functional properties of the cells of helminths, such as formation of the cytoskeleton, formation of the mitotic spindle and the uptake and intracellular transport of nutrients and metabolic products. Fenbendazole is effective and has a dose dependent effect on adult stages.

### 5.2 Pharmacokinetic particulars

After oral administration fenbendazole is only partially absorbed. Following absorption, fenbendazoleis rapidly metabolised in the liver mainly to its sulphoxide (oxfendazole) and further to its sulphone (oxfendazole sulphone). Fenbendazole and its metabolites are distributed throughout the body, reaching highest concentrationsin the liver. The elimination of fenbendazole and its metabolites occurs primarily via the faeces.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Benzyl alcohol (E1519)
Azorubine 85% (E122)
Aluminium magnesium silicate
Xanthan gum
Propylene glycol
Simethicone
Sorbitan Oleate
Polysorbate 80
Purified water

### 6.2 Major incompatibilities

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

## 6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

## 6.4 Special precautions for storage

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

## 6.5 Nature and composition of immediate packaging

Type III amber glass bottles of 10 ml, 30 ml and 50 ml closed with tamper-evident HDPE screw capswith ring and colourless LDPE syringe insert. A 1 ml dosing syringe is supplied with each 10 mlbottle, a 1 ml and a 5 ml dosing syringe are supplied with each 30 ml or 50 ml bottle.
Cardboard box containing 10 separate boxes, each containing 1 bottle.

Pack sizes:
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.

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

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

## 7. MARKETING AUTHORISATION HOLDER

Avimedical B.V.
Abbinkdijk 1
7255 LX Hengelo (Gld)
THE NETHERLANDS

## 8. MARKETING AUTHORISATION NUMBER

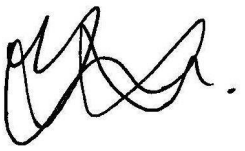
Vm 43564/4002

## 9. DATE OF FIRST AUTHORISATION

28 April 2017

## 10. DATE OF REVISION OF THE TEXT

June 2022



Approved: 29 June 2022