

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 substances:

Fenbendazole 25 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Benzyl alcohol (E1519)	20 mg
Azorubine 85% (E122)	12 µg
Aluminium magnesium silicate	
Xanthan gum	
Propylene glycol	
Simethicone	
Sorbitan Oleate	
Polysorbate 80	
Purified water	

Slightly pink viscous suspension.

3. CLINICAL INFORMATION

3.1 Target species

Pigeons.

3.2 Indications for use for each target species

Treatment of the following gastro-intestinal nematodes in pigeons:

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

3.3 Contraindications

Birds should not be treated with fenbendazole during moulting.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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

Safety of the veterinary medicinal 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 veterinary medicinal 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. Veterinary medicinal 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 veterinary medicinal product may be toxic to humans after ingestion.
This veterinary medicinal 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 of skin and/or eye contact, immediately rinse with plenty of clean water. Due to the risk of accidental ingestion, never leave a loaded syringe unattended.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigeons:
None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during lay.

Laying birds:
Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Exacerbation of paracetamol hepatotoxicity by fenbendazole cannot be excluded.

3.9 Administration routes and dosage

Oral use.

To ensure a correct dosage, 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 veterinary medicinal 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not authorised for use in birds producing food for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AC13

4.2 Pharmacodynamics

Fenbendazole is an anthelmintic belonging to the benzimidazole-carbamate group. It acts by interfering 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.

4.3 Pharmacokinetics

After oral administration fenbendazole is only partially absorbed. Following absorption, fenbendazole is rapidly metabolised in the liver mainly to its sulfoxide (oxfendazole) and further to its sulphone (oxfendazole sulphone).

Fenbendazole and its metabolites are distributed throughout the body, reaching highest concentrations in the liver. The elimination of fenbendazole and its metabolites occurs primarily via the faeces.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 Special precautions for storage

Keep the bottle tightly closed.

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

5.4 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 caps with ring and colourless LDPE syringe insert. A 1 ml dosing syringe is supplied with each 10 ml bottle, 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.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Avimedical B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 43564/4002

8. DATE OF FIRST AUTHORISATION

28 April 2017

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

June 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 27 July 2026