

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Curofen 50 mg/g oral powder for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance:

Fenbendazole 50 mg

Excipients:

Qualitative composition of excipients and other constituents
Glucose monohydrate.
Silica, colloidal anhydrous

A white powder.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each target species

For the treatment of benzimidazole susceptible mature and immature (L₄) forms of the following nematodes of the gastrointestinal and respiratory tracts of pigs:

Hyoststrongylus rubidus (red stomach worm)

Oesophagostomum spp. (nodular worms)

Ascaris suum (eelworm)

Trichuris suis (whipworm)

Metastrongylus apri (Lungworm)

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, other benzimidazoles or to any of the excipients.

3.4 Special warnings

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of body weight, misadministration of the veterinary medicinal product, or lack of calibration of the dosing device (if any).

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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

Embryotoxic effects cannot be excluded. Pregnant women must take extra precautions when handling this veterinary medicinal product.

This veterinary medicinal product may cause hypersensitivity (allergy) reactions. People with known hypersensitivity to fenbendazole should avoid contact with the veterinary medicinal product.

Avoid skin contact when handling this veterinary medicinal product.

Personal protective equipment, consisting of protective clothing, impervious gloves and a face-mask should be worn when handling or mixing the veterinary medicinal product to avoid direct contact with the skin and inhalation of any dust. It is recommended to use either a disposable half-mask respirator conforming to European Standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143.

In case of skin and/or eye contact, rinse immediately with plenty of water.

Wash hands after use.

Accidental ingestion of the veterinary medicinal product should be avoided. In the event of accidental ingestion rinse mouth with plenty of clean water, seek medical advice and show the package leaflet or label to the physician.

Special precautions for the protection of the environment:

The veterinary medicinal product should not be allowed to enter surface waters as it has harmful effects on fish and other aquatic organisms.

3.6 Adverse events

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 or immediate packaging for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

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 by adding to small quantities of feed for immediate consumption by individual pigs.

Individual Treatment – single dose

The recommended therapeutic dose is 5 mg fenbendazole per kg bodyweight as a single dose individual treatment which is equivalent to 1g per 10kg bodyweight, 5g per 50 kg bodyweight or 20g per 200 kg bodyweight.

To ensure a correct dosage, bodyweight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended.

The recommended amount of veterinary medicinal product should be added to a small quantity of the estimated daily amount of food for each individual animal in a bucket or a similar container and mixed thoroughly prior to being offered for immediate consumption.

Medicated feed should be freshly prepared before administration.

Part-consumed feed must be disposed of with other waste feed and not given to other animals.

Dosing table:

Pig Bodyweight (kg)	Amount (g) of veterinary medicinal product
50 kg	5g
100 kg	10g
150 kg	15g
200 kg	20g

The veterinary medicinal product is to be administered only for the treatment of individually fed animals or a small group of animals where the intake by individual animals can be effectively controlled. Larger groups should be treated with medicated feeding stuff manufactured using an appropriate anthelmintic premix.

Treatment for specific infections

For the treatment of *Trichuris suis*, it is recommended that the dosage is divided and administered over seven days.

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

None known.

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

Meat and offal: 6 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP52AC13.

4.2 Pharmacodynamics

Fenbendazole is a broad spectrum anthelmintic from the benzimidazole-carbamate group. Benzimidazoles bind to nematode tubulin, a protein necessary for the formation and viability of microtubules. This occurs primarily in absorptive intestinal cells resulting in a complete absence of microtubules in the intestinal cells of the nematode, which means that these cells cannot absorb nutrients, a consequent reduction in glycogen and effective starvation of the parasites. Structural differences have been shown to exist between tubulin from mammalian and helminth sources, thus resulting in the preferential toxicity of fenbendazole to the helminth and not to the host. Fenbendazole may also inhibit energy production in helminths by inhibition of glucose uptake and glycogen breakdown.

4.3 Pharmacokinetics

Fenbendazole is poorly soluble in water and consequently is poorly absorbed when administered orally. The main breakdown products are the sulfoxide (oxfendazole) and sulphone.

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

Store in a dry place.
Store in the original container in order to protect from light.

5.4 Nature and composition of immediate packaging

200 g and 1 kg bag composed of clear low density polyethylene (LDPE) laminated with metallised polyester.
1 kg bag composed of clear low density polyethylene (LDPE).

Package sizes:

5 x 200 g LDPE laminated bags in a cardboard box
1 kg LDPE laminated bag
1 kg LDPE bag inside a white polypropylene container

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.

The veterinary medicinal product should not enter water courses as fenbendazole may be dangerous for fish and other aquatic organisms.

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

Univet Limited

7. MARKETING AUTHORISATION NUMBERS

Vm 05150/5004
Vm 05150/3004

8. DATE OF FIRST AUTHORISATION

04 December 2015

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: 16 July 2026