1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Curazole 50 mg/g premix for medicated feeding stuff 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
Colloidal anhydrous silica

A white powder.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each target species

For the control of benzimidazole susceptible mature and developing immature forms of the following nematodes of the gastrointestinal and respiratory tracts of pigs:

Hyostrongylus rubidus (red stomach worm)
Oesophagostomum spp. (nodular worms)
Ascaris suum (eel worm)
Trichuris suis (whip worm)
Metastrongylus apri (lungworm)

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance 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:

Avoid skin contact when handling this veterinary medicinal product.
When incorporating into feed, care must be taken not to inhale any dust. Personal protective equipment consisting of a facemask should be worn when handling the veterinary medicinal product. Wash hands and wash all exposed skin after use.

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 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

Pregnancy:

Can be used during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

In-feed use.
For oral administration after incorporation into complete feed for pigs. Feed medicated with this veterinary medicinal product can be pelleted. Pelleting should not be conducted at temperatures in excess of 70 °C.
The recommended therapeutic dose is 5 mg fenbendazole per kg bodyweight.

To ensure a correct dosage, body weight should be determined as accurately as possible.
If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.

To achieve this dose:

a) mass/whole herd medication with a single dose (on one day).

Use the following formula to calculate how much veterinary medicinal product to add per tonne of feed:

$$\frac{[0.1\ \text{g} * \text{veterinary medicinal product} / \text{Number of treatment days}] \times \text{Average Bodyweight (kg) of treated animals}}{}$$

Kg of veterinary medicinal product /tonne = ----------
Average daily feed intake (kg)

*For a single treatment, the dose rate is 5 mg of fenbendazole/kg bw, equivalent to 100 mg or 0.1g/ kg bw.

- For the treatment of growing and finishing pigs, this veterinary medicinal product should be mixed into feed at the rate of 2 kg per tonne of feed.

It is recommended that the 2 kg of powder is initially mixed into 20 kg of dry feed. This premix should be mixed into the bulk feed. This quantity of feed will treat on a single occasion:

800 pigs of 25 kg bodyweight each consuming 1.25 kg medicated feed. 400 pigs of 50 kg bodyweight each consuming 2.5 kg medicated feed.

- For the treatment of sows of 150 kg bodyweight, each consuming 2 kg medicated feed, mix 7.5 kg of this veterinary medicinal product into 1 tonne of feed. This quantity of medicated feed will treat 500 sows on a single occasion.

- For the treatment of sows of 200 kg bodyweight, each consuming 2.5 kg medicated feed, mix 8 kg of this veterinary medicinal product into 1 tonne of feed. This quantity of medicated feed will treat 400 sows on a single occasion.

OR

(b) Mass/whole herd medication - split dosage over 3 or 7 days i.e. 1.7 mg/kg/day for 3 days or 0.7 mg/kg/day for 7 days. The administration of powder in equal parts over three or seven days is as effective as a single dose on one day.

Use the following formula to calculate how much veterinary medicinal product to add per tonne of feed:

Kg of veterinary medicinal product /tonne = [0.1g * veterinary medicinal product / x Number of treatment days] Average Bodyweight (kg) of treated animals
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Average daily feed intake (kg)

Pigs	**5% Powder per tonne of feed**	**Fenbendazole per tonne of feed**	**No. of animals treated per tonne of**
3-DAY TREATMENT Growing and finishing pigs (30 kg bodyweight)	666 g	33.3 g	222
Sows (150 kg)	2500 g	125 g	166
7-DAY TREATMENT			
Growing and finishing pigs (30 kg bodyweight)	285 g	14.3 g	95
Sows (150 kg)	1050 g	52.5 g	70

When incorporated into feed at a rate of below 2 kg per tonne of final feed, the veterinary medicinal product must only be mixed by a manufacturer who is approved to mix at that level.

Treatment for specific infections

For the control 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

Benzimadazole carbamates act primarily by inhibiting the polimerization of tubulin to form microtubules. The various activities attributed to these molecules are due to a specific affinity for the tubulin of the target parasites. The overall effect of this action is to effectively starve the parasite to death.

4.3 Pharmacokinetics

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after incorporation into meal or pelleted feed: 1 month.

5.3 Special precautions for storage

Keep the container tightly closed.
Protect from light.
Store in a dry place.

5.4 Nature and composition of immediate packaging

Supplied in 1, 2 and 4 kg polypropylene containers and 20 kg cardboard drums and 25 kg triple layered paper bags, lined with a LD polyethylene bag.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

Univet Ltd

7. MARKETING AUTHORISATION NUMBER(S)

VPA10990/030/001

8. DATE OF FIRST AUTHORISATION

26/06/1998

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

15/10/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).