SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Curofen 50 mg/g Premix for Medicated Feeding Stuff for Pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance:

Fenbendazole 50 mg

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Premix for Medicated Feeding stuff
A white powder.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

4.2 Indications for use, specifying the target species

For the treatment of benzimidazole susceptible mature and immature (L_4) 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)

4.3 Contraindications

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

4.4 Special warnings for each target species

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 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.

4.5 Special precautions for use

Special precautions for use in animals

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.

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

Avoid skin contact when handling this product.

This product may be toxic to humans after ingestion.
Accidental ingestion of the product should be avoided.

When handling or mixing, care should be taken to avoid direct contact with the skin and inhalation of any dust by wearing protective clothing, including impervious gloves and a face-mask. 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.

Other Precautions

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

User Safety Warnings for Feedmill Operators
When handling or mixing, suitable dust extraction equipment should be used. Where this is not available, 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 should be used.

In case of skin and/or eye contact, immediately rinse with plenty of water.
In the event of accidental ingestion, rinse mouth with plenty of clean water and seek medical advice.'

Wash hands and all exposed skin after use.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

The product can be used in pregnant or lactating sows

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration after incorporation into complete feed for pigs. Feed medicated with this 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 administration of a correct dose, 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 Curofen 50mg/g to add per tonne of feed:

$$\text{kg of Curofen/tonne} = \frac{[0.1\ \text{g} * \text{Curofen 50mg/g} / \text{Number of treatment days}] \times \text{Average Bodyweight (kg) of treated animals}}{\text{Average daily feed intake (kg)}}$$

*For a single treatment, the dose rate is 5 mg of fenbendazole/kg bw, equivalent to 100 mg or 0.1g Curofen 50mg/g kg/ bw.

- For the treatment of growing and finishing pigs, this 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 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 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 Curofen 50mg/g to add per tonne of feed:

$$\text{kg of Curofen /tonne} = \frac{[0.1\text{ g} * \text{Curofen 50mg/g} / \text{Number of treatment days}] \times \text{Average Bodyweight (kg) of treated animals}}{\text{Average daily feed intake (kg)}}$$

Pigs	**50mg/g Premix per tonne of feed**	**Fenbendazole per tonne of feed**	**No. of animals treated per tonne of feed**
3-DAY TREATMENT			
Growing and finishing pigs (30 kg bodyweight)	666 g	33.3 g	222
Sows (150 kg)	2500 g	125g	166
7-DAY TREATMENT			
Growing and finishing pigs (30 kg	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 product must only be mixed by a manufacturer who is approved to mix at that level.

Treatment for specific infections
For the treatment

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

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

None known

4.11 Withdrawal period

Meat and offal: 6 days.

5. PHARMACOLOGICAL PROPERTIES

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

5.1 Pharmacodynamic properties

Fenbendazole is an anthelmintic (wormer) belonging to the benzimidazole-carbamate group. It acts by binding to beta-tubulin, thereby inhibiting the polymerisation of tubulin to microtubules and subsequently interfering with energy metabolism.

5.2 Pharmacokinetic particulars

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glucose Monohydrate
Colloidal anhydrous silica

6.2 Major Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary 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
Shelf-life after incorporation into meal or pellets: 1 month.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions. Store in a dry place. Store in the original container in order to protect from light. Keep the container tightly closed.

6.5 Nature and composition of immediate packaging

1 kg LDPE bag inside a polypropylene container
2 kg LDPE bag inside a polypropylene container
4 kg LDPE bag inside a polypropylene container
20 kg LDPE bag inside a cardboard drum
25 kg LDPE bag inside a triple-layered paper bag

Not all pack sizes may be marketed

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. The product should not enter water courses as this may be dangerous for aquatic organisms.

7. MARKETING AUTHORISATION HOLDER

Univet Ltd
Tullyvin
Cootehill
Co. Cavan
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 05150/4005

9. DATE OF FIRST AUTHORISATION

28 June 2017

10. DATE OF REVISION OF THE TEXT

July 2022

Approved 22 July 2022