Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Curazole 5% w/w Premix for Medicated Feed

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance

Fenbendazole	50 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Premix for medicated feed

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs.

4.2 Indications for use, specifying the 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)

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

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:

None.

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

Avoid skin contact when handling this product.
When incorporating into feed, care must be taken not to inhale any dust. It is recommended that a facemask be worn during the dispensing and mixing of the product. Wash hands and wash all exposed skin after use.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

The product may be used safely in sows during pregnancy.

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 Curazole 5% to add per tonne of feed:

$$\text{Kg of Curazole/tonne} = \frac{[0.1\text{ g *Curazole 5\% / Number of treatment days}] \times \text{Average Bodyweight (kg) of treated animals}}{\text{Average daily feed intake (kg)}}$$

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

- For the treatment of growing and finishing pigs, Curazole 5% w/w Powder 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 Curazole 5% w/w Powder 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 Curazole 5% w/w Powder 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 Curazole 5% to add per tonne of feed:

$$\text{Kg of Curazole/tonne} = \frac{[0.1\text{ g *Curazole 5\% / Number of treatment days}] \times \text{Average Bodyweight (kg) of treated animals}}{\text{Average daily feed intake (kg)}}$$

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

Pigs	5% Powder 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	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 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.

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

Not applicable.

4.11 Withdrawal Period(s)

Meat and offal: 6 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Anthelmintics; Fenbendazole.
ATCvet code: QP52AC13

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic properties

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 Incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

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

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Univet Ltd
Tullyvin
Cootehill
Co Cavan

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10990/030/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th June 1998

Date of last renewal: 25th June 2008

10 DATE OF REVISION OF THE TEXT

February 2016