1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Curazole 50 mg/g oral powder for pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Fenbendazole 50 mg
Excipient(s):
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Powder.
A white powder.

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 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

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. 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.
Wash hands and wash all exposed skin after use.

Other precautions

None.

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

This product is not recommended for concurrent administration with any other oral medication.

4.9 Amounts to be administered and administration route

For oral administration as a top dressing 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 1 g of the product per 10 kg bodyweight or 5 g of the product per 50 kg bodyweight or 20 g of the product per 200 kg bodyweight.

To ensure the correct dosage and to avoid possible under-dosing, the bodyweight and the amount of product administered should be determined as accurately as possible. To determine the correct amount of product for bodyweights not indicated on the table, a calibrated weighing scale should be used.
As a guide to dosing pigs of a weight suitable for using the enclosed 5 g or the 20 g measuring devices, see table.
Dosing Table

Pig Bodyweight (kg)	Amount (g) of the product	Measuring Devices: 5 g – small scoop 20 g – large scoop
50 kg	5 g	1 x 5 g
100 kg	10 g	2 x 5 g
150 kg	15 g	3 x 5 g
200 kg	20 g	1 x 20 g

For use on individual animals on farms where only a small number of pigs are to receive the medicine. Larger groups should be treated with medicated feeding stuff manufactured using an appropriate anthelmintic premix.

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

Do not exceed the stated dose.

4.11 Withdrawal period(s)

Pigs:

Meat and offal: 6 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintic
ATCvet code: QP52AC13

5.1 Pharmacodynamic properties

Benzimadazole carbamates act primarily by inhibiting the polymerisation 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 PH. EUR.
COLLOIDAL ANHYDROUS SILICA PH.EUR.

6.2 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

6.4 Special precautions for storage

Do not store above 25°C.
Store in a dry place.
Store in the original container.
Protect from light.

6.5 Nature and composition of immediate packaging

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

1 kg polypropylene container lined with a low density polyethylene bag supplied with a 5 g and 20 g polypropylene measuring device.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Univet Limited
Tullyvin
Cootehill
Co. Cavan.
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10990/044/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th July 2011
Date of last renewal: 29th July 2016

10 DATE OF REVISION OF THE TEXT

May 2017