

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ecozole 4% w/w Premix for Medicated Feeding Stuff.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each 1g contains

Fenbendazole 0.04g

Excipient(s):

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Premix for Medicated Feeding Stuff

A white to off white powder.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

4.2 Indications for use, specifying the target species

A broad spectrum anthelmintic for the treatment of pigs infected with mature and immature forms of nematodes of the gastro-intestinal and respiratory tracts:

Hyostrogylus rubidus (Red Stomach worm)

Oesophagostomum sp. (Nodular worms)

Ascaris suum (large roundworm)

Trichuris suis (Whipworm)

Also effective in the control of *Metastrongylus apri* (Lungworm).

An ovicidal effect on nematode eggs.

4.3 Contraindications

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

4.4 Special warnings <for each target species>

None.

4.5 Special precautions for use

(i) Special precautions for use in animals

When preparing medicated feed for pigs which are to be administered over a number of days, to ensure thorough dispersion a pre-mix should be prepared first. Once mixed, this should then be incorporated with the remaining feed.

The product can be incorporated into pelleted feed preconditioned with steam at a temperature not greater than 75°C.

Only to be incorporated by a manufacturer who are approved to mix at a rate of below 2 kg per tonne of final feed.

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

Incorporating into the feed must be performed by a suitably approved manufacturer.

Impervious gloves must be worn when handling this product or feed containing this product.

When handling or mixing, care should be taken to avoid direct contact with the skin and inhalation of any dust by wearing protective clothing, rubber gloves and 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 exposed skin after handling medicated feedstuffs.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

Ecozole 4% Powder can be safely used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

A manufacturer who is approved to incorporate directly at any concentration, veterinary medicinal products or premixtures containing such products must be responsible for mixing when incorporation is less than 2kg per tonne for final feed.

To be administered orally, mixed with feed. The dose rate for administration is 5 mg fenbendazole per kg bodyweight. The product may be administered to pigs either as a single dose or by divided dosage over 7 days. It may also be administered to sows over 14 days.

For the treatment of infections with *Trichuris* and for control of *Metastrongylus apri* the dose of 5 mg/kg should be divided and spread over 7 days.

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

Benzimidazoles have a wide safety margin.

4.11 Withdrawal period

Meat and offal: 3 days

5. PHARMACOLOGICAL PROPERTIES

ATC vet code: QP52AC13

5.1 Pharmacodynamic properties

A broad spectrum anthelmintic from the benzimidazole 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.

5.2 Pharmacokinetic particulars

Fenbendazole is only partially absorbed following oral administration. The absorbed fenbendazole is metabolised to the active compound, oxfendazole (sulfoxide) and the sulfone. In pigs, a significant proportion of the dose of fenbendazole is excreted unchanged in the faeces, and a very small proportion in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate

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 finished feed: 12 months.

6.4. Special precautions for storage

Store in a dry place.

Do not store above 25°C.

The product will remain stable in the finished feed for 12 months.

6.5 Nature and composition of immediate packaging

The product is presented in pack sizes of 500 g, 1 kg and 10 kg packed into low density polyethylene bag in a polypropylene tub closed with polypropylene push fit cap.

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.

7. MARKETING AUTHORISATION HOLDER

Chanelle Animal Health Ltd

7 Rodney Street

Liverpool

L1 9HZ

8. MARKETING AUTHORISATION NUMBER


Vm 11990/4012

9. DATE OF FIRST AUTHORISATION

Date: 06 July 1995

10 DATE OF REVISION OF THE TEXT

Date: March 2016

 09 March 2016