PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ecozole 4% w/w Premix for Medicated Feeding Stuff

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 g of product provides 0.04 g of the active ingredient Fenbendazole.

3. PHARMACEUTICAL FORM

Premix for Medicated Feeding Stuff

4. PACKAGE SIZE

5. TARGET SPECIES

Pigs

6. INDICATION(S)

Ecozole 4% w/w Premix for Medicated Feeding Stuff is a broad spectrum anthelmintic effective in the treatment of mature and immature stages of gastro-intestinal and respiratory tract nematodes in pigs, it also has an ovicidal effect.

Ecozole 4% w/w Premix for Medicated Feeding Stuff is active against:- Hyostrongylus rubidus. (red stomach worm), Oesophagastomum sp. (nodular worms), Ascaris suum (large roundworm), Trichuris suis (whipworm) and Metastrongylus apri (lungworm).

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration only. Ecozole 4% w/w Premix for Medicated Feeding Stuff should be mixed with the feed.

Ecozole 4% w/w Premix for Medicated Feeding Stuff is readily consumed by pigs in normal feed.

DOSAGE: No dietary control is required before or after treatment. Ecozole 4% w/w Premix for Medicated Feeding Stuff is suitable for herd medication of pigs or individual treatment of animals. The standard dose rate is 5 mg fenbendazole/kg bodyweight. Pigs can be dosed in several ways:

(a) Single dose treatment.

(b) 7 day treatment, i.e. the dose is administered in the feed over 7 days.

(c) 14 day treatment, i.e. the dose is administered in the feed over 14 days.

See package leaflet for details on dosing.

8. WITHDRAWAL PERIOD

Meat and offal: 3 days

9. SPECIAL WARNING(S), IF NECESSARY

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

Operator Warnings: See package leaflet for operator warnings.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Store in a dry place. Do not store above 25^{o}C.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

POM-VPS

For animal treatment only

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
H62 FH90
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08749/3072

17. MANUFACTURER’S BATCH NUMBER

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
H62 FH90
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ecozole 4% w/w Premix for Medicated Feeding Stuff

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each 1g of Ecozole 4% w/w Premix for Medicated Feeding Stuff contains 0.04g active ingredient Fenbendazole.

Ecozole 4% w/w Premix for Medicated Feeding Stuff is a powder formulation of fenbendazole for incorporation into feedstuffs for oral administration.

4. INDICATION(S)

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

Hyostrongylus rubidus (red stomach worms)

Oesophagostomum spp. (nodular worms)

Ascaris suum (large roundworm)

Trichuris suis (whipworm)

Ecozole 4% w/w Premix for Medicated Feeding Stuff is also effective in the control of *Metastrongylus apri* (lungworm).

Ecozole 4% w/w Premix for Medicated Feeding Stuff has an ovicidal effect on nematode eggs.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The dose rate is 5 mg fenbendazole/kg bodyweight.

Routine treatment - herd medication:

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

(a) *Single dose treatment:*

For the treatment of growing and finishing pigs, mix 2.5 kg Ecozole 4% w/w Premix for Medicated Feeding Stuff into 1 tonne of feed. If home mixing, it is recommended that the 2.5 kg powder is initially mixed into 25 kg dry feed. This premix should then 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 9.375 kg Ecozole 4% 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 10 kg Ecozole 4% w/w Premix for Medicated Feeding Stuff into 1 tonne feed. This quantity of medicated feed will treat 400 sows on a single occasion.

(b) *7 day treatment:*

The standard dosage (5 mg fenbendazole/kg bodyweight) can be divided and administered in the feed over 7 days. The medicated feed should be prepared as follows:

PIGS	4% Powder per tonne of feed	Fenbendazole per tonne of feed	Number of animals treated/ tonne feed
Growing and Finishing Pigs	360 g	14.4 g	95
Sows	1340 g	53.6 g	70

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

(c) *14 day treatment of sows:* The standard dosage (5 mg fenbendazole/kg bodyweight) can be divided and administered to sows in the feed over 14 days.

The medicated feed should be prepared as follows:

PIGS	4% Powder per tonne of feed	Fenbendazole per tonne of feed	Number of animals treated/ tonne feed
Sows 150 kg	536 g	21.4 g	28
Sows 200 kg	714 g	28.6 g	28

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

Routine treatment - individual medication:

Ecozole 4% w/w Premix for Medicated Feeding Stuff may be administered to individual pigs, added to the feed.

The dose rate is 5 mg of fenbendazole per kg bodyweight which is equivalent to approximately 3 g of Ecozole 4% w/w Premix for Medicated Feeding Stuff per 25 kg bodyweight.

Treatment for specific infections:

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.

To treat growing and finishing pigs mix 1.5 kg Ecozole 4% w/w Premix for Medicated Feeding Stuff into 1 tonne of feed. 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.

This quantity of medicated feed will treat:

266 pigs of 25 kg bodyweight each consuming 1.25 kg medicated feed per day for 3 days. 133 pigs of 50 kg bodyweight each consuming 2.5 kg medicated feed per day

for 3 days. For the treatment of sows of 150 kg bodyweight, each consuming 2 kg medicated feed per day, mix 5.625 kg Ecozole 4% w/w Premix for Medicated Feeding Stuff into 1 tonne feed. This quantity of medicated feed will treat 166 sows for a 3 day period.

For the treatment of sows of 200 kg bodyweight, each consuming 2.5 kg medicated feed per day, mix 6 kg Ecozole 4% w/w Premix for Medicated Feeding Stuff into 1 tonne feed. This quantity of medicated feed will treat 133 sows for a 3 day period.

9. ADVICE ON CORRECT ADMINISTRATION

No dietary control is required before or after treatment. Assess bodyweight as accurately as possible before calculating the dosage.

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

For animal treatment only.

When preparing medicated feed for pigs which are to be administered over a number of days, to ensure thorough dispersion the product should first be mixed with 2.5 kg per tonne of feed before incorporation in the final mix.

The product can be incorporated into pelleted feed preconditioned with steam at a temperature not greater than 75°C. The product will remain stable in the finished feed for 12 months. Only to be incorporated by a manufacturer who is approved to mix at a rate of below 2 kg per tonne of final feed.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 3 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of sight and reach of children.

Do not store above 25°C. Store in a dry place.

12. SPECIAL WARNING(S)

Operator precautions:

Feed mill operators - 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 to European Standard EN 140 with a filter to EN 143.

Home mixing operators - When handling or mixing, suitable skin, eye and respiratory equipment must be used. Impervious gloves must be worn when handling this product or feed containing this product. Direct contact with skin should be kept to a minimum. Wash hands after handling medicated feedstuffs. Keep out of reach and sight of the children. For animal treatment only.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

15. OTHER INFORMATION

POM - VPS

Vm 08749/3072

Pack sizes include 500 g, 1 kg and 10 kg.

Not all pack sizes may be marketed.

For Animal Treatment Only.

Gavin Hall
Approved: 01 October 2025