LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE COMBINED LABEL/PACKAGE LEAFLET

20 kg cardboard drums and 25 kg triple layered paper bags, lined with a low density polyethylene bag

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

Marketing authorisation holder and manufacturer responsible for batch release:
Univet Ltd.
Tullyvin
Cootehill
Co. Cavan
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Fenbendazole

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

A white powder
Each g contains 50 mg of fenbendazole.

4. PHARMACEUTICAL FORM

Premix for Medicated Feeding Stuff

5. PACKAGE SIZE

20kg
25kg

6. INDICATIONS

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)

7. CONTRAINDICATIONS

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

8. ADVERSE REACTIONS

None known.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

9. TARGET SPECIES

Pigs.

10. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

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 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	125 g	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.

11. ADVICE ON CORRECT ADMINISTRATION

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.

12. WITHDRAWAL PERIOD

Meat and offal: 6 days.

13. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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.

Shelf life after first opening the immediate packaging: 28 days
Once opened, use by: …….

Shelf-life after incorporation into meal or pellets: 1 month.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

14. SPECIAL WARNINGS

For animal treatment only.

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.

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.

Pregnancy:

The product can be used in pregnant or lactating sows.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose (symptoms, emergency procedures, antidotes):

None known.

Incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products**.**

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

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.

16. DATE ON WHICH THE TEXT WAS LAST APPROVED

July 2022

17. OTHER INFORMATION

Fenbendazole is an anthelmintic (wormer) belonging to the benzimidazole-carbamate group.

Supplied in 20 kg cardboard drums and 25 kg triple layered paper bags, lined with a low density polyethylene bag

Pack Sizes:
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.

18. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

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

Keep out of the sight and reach of children

20. EXPIRY DATE

EXP {month/year}

21. MARKETING AUTHORISATION NUMBER(S)

Vm 05150/4005

22. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> ><BN> {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1, 2 and 4 kg LDPE Bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Fenbendazole

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each g contains 50 mg of fenbendazole.

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff

4. PACKAGE SIZE

1kg
2kg
4kg

5. TARGET SPECIES

Pigs.

6. INDICATIONS

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)

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 6 days.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 28 days.
Once opened, use by:…

11. SPECIAL STORAGE CONDITIONS

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.

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

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only
To be supplied only on veterinary prescription.

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

Univet Ltd.
Tullyvin
Cootehill
Co. Cavan
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05150/4005

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> ><BN> {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

POLYPROPYLENE CONTAINER (a package leaflet will be included in the polypropylene container)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Fenbendazole

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each g contains 50 mg of fenbendazole.

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff

4. PACKAGE SIZE

1 kg
2kg
4 kg

5. TARGET SPECIES

Pigs.

6. INDICATIONS

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)

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 6 days.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after opening the immediate packaging: 28 days
Once opened, use by:…

11. SPECIAL STORAGE CONDITIONS

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

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

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

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

Univet Ltd.
Tullyvin
Cootehill
Co. Cavan
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05150/4005

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> ><BN> {number}

B. PACKAGE LEAFLET for the following pack types only:

1, 2 and 4 kg polypropylene containers, lined with a low density polyethylene bag

PACKAGE LEAFLET FOR:

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

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

Marketing authorisation holder and manufacturer responsible for batch release:
Univet Ltd.
Tullyvin
Cootehill
Co. Cavan
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Fenbendazole

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

A white powder
Each g contains 50 mg of fenbendazole.

4. INDICATIONS

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

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

None known.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs.

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

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	125 g	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.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

10. WITHDRAWAL PERIOD

Meat and offal: 6 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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
Do not use this veterinary medicinal product after the expiry date which is stated on the label after "EXP". The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days
Shelf-life after incorporation into meal or pellets: 1 month.

12. SPECIAL WARNINGS

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.

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.

Pregnancy:

The product can be used in pregnant and lactating sows.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose (symptoms, emergency procedures, antidotes):

None known.

Incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2022

15. OTHER INFORMATION

Fenbendazole is an anthelmintic (wormer) belonging to the benzimidazole-carbamate group.

Marketing Authorisation Number: Vm 05150/4005

Supplied in 1, 2 and 4 kg polypropylene containers, lined with a low density polyethylene bag

Pack Sizes:

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.

Approved 22 July 2022