LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE COMBINED LABEL/PACKAGE LEAFLET

1 kg FOIL BAG (polyethylene liner laminated with metallised polyester**)**

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 oral powder for pigs

Fenbendazole

3. STATEMENT OF ACTIVE SUBSTANCES

Each g contains

Active substance:
Fenbendazole 50mg

A white powder

4. PHARMACEUTICAL FORM

Oral powder.

5. PACKAGE SIZE

1 Kg

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 (eelworm)
Trichuris suis (whipworm)
Metastrongylus apri (Lungworm)

7. CONTRAINDICATIONS

Do not use in known cases of hypersensitivity to the active substance, other benzimidazoles 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 use by adding to small quantities of feed for immediate consumption by individual pigs.

<u>Individual Treatment – single dose</u>
The recommended therapeutic dose is 5 mg fenbendazole per kg bodyweight as a single dose individual treatment which is equivalent to 1g of product per 10kg bodyweight or 5g of product per 50 kg bodyweight or 20g of product per 200 kg bodyweight.

To ensure the correct dosage and to avoid possible under-dosing, the bodyweight and the amount of product to be administered should be determined as accurately as possible. To accurately measure the correct amount of product, a suitably calibrated weighing scale should be used.
The recommended amount of veterinary medicinal product should be added to a small quantity of the estimated daily amount of food for each individual animal in a

bucket or a similar container and should be mixed thoroughly prior to being offered for immediate consumption.
Medicated feed should be freshly prepared before administration.
Part-consumed feed must be disposed of with other waste feed and not given to other animals.
Dosing table:

Pig Bodyweight (kg)	Amount (g) of product
50 kg	5g
100 kg	10g
150 kg	15g
200 kg	20g

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

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.

12. WITHDRAWAL PERIOD

Meat and offal: 6 days.

13. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a dry place.
Store in the original container in order to protect from light.
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:

None.

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.

This product may cause hypersensitivity (allergy) reactions. People with known hypersensitivity to fenbendazole should avoid contact with the veterinary medicinal product.

Avoid skin contact when handling 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, 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.
In case of skin and/or eye contact, immediately rinse with plenty of water.
Wash hands after use.

Accidental ingestion of the product should be avoided. In the event of accidental ingestion, rinse mouth with plenty of clean water and seek medical advice."

Other Precautions

The veterinary medicinal product should not be allowed to enter surface waters as it has harmful effects on fish and other aquatic organisms.

Pregnancy:

The product can be used in pregnant or lactating sows.

Interaction with other medicinal products and other forms of interaction:

Exacerbation of paracetamol hepatotoxicity by fenbendazole cannot be excluded

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 fish and other aquatic organisms.

16. DATE ON WHICH THE LABEL WAS LAST APPROVED

March 2021

17. OTHER INFORMATION

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

Pack Size:
1 kg LDPE laminated bag

Pack sizes authorised:
5 x 200g LDPE laminated bags in a cardboard box
1 kg LDPE laminated bag
1 kg LDPE bag inside a white polypropylene container

Not all pack types may be marketed.

For any information about this veterinary medicinal product, please contact the local representative holder.

18. 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.

19 THE WORDS "KEEP OUT OF SIGHT AND REACH OF CHILDREN"

Keep out of sight and reach of children.

20. EXPIRY DATE

EXP {month/year}

Shelf life after first opening the immediate packaging: 28 days

Once opened, use by: …….

21. MARKETING AUTHORISATION NUMBER(S)

Vm 05150/4004

22 MANUFACTURER'S BATCH NUMBER

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

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

200g Foil Bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Curofen 50 mg/g oral powder for pigs

Fenbendazole

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains 50 mg of fenbendazole.

3. PHARMACEUTICAL FORM

Oral powder.

4. PACKAGE SIZE

200 g

5. TARGET SPECIES

Pigs.

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

Store in a dry place.
Store in the original container in order to protect from light.

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.

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 05150/4004

17. MANUFACTURER'S BATCH NUMBER

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

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1kg LDPE Bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Curofen 50 mg/g oral powder for pigs

Fenbendazole

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains 50 mg of fenbendazole.

3. PHARMACEUTICAL FORM

Oral powder.

4. PACKAGE SIZE

1kg

5. TARGET SPECIES

Pigs.

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

Store in a dry place.
Store in the original container in order to protect from light.

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.

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 05150/4004

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) and outer **CARDBOARD BOX** for the 200g laminated bags (one package leaflet will be included in the cardboard box)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Curofen 50 mg/g oral powder for pigs

Fenbendazole

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains 50 mg of fenbendazole.

3. PHARMACEUTICAL FORM

Oral powder

4. PACKAGE SIZE

1 kg
5 x 200g

5. TARGET SPECIES

Pigs.

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

Store in a dry place.
Store in the original container in order to protect from light.

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.

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 05150/4004

17. MANUFACTURER'S BATCH NUMBER

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

B. PACKAGE LEAFLET for the following pack types only:

5 x 200 g LDPE laminated bags in cardboard box
and
1 kg LDPE bag inside a white polypropylene container.

PACKAGE LEAFLET FOR:
Curofen 50 mg/g oral powder 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 oral powder for pigs

Fenbendazole

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each g contains

Active substance:
Fenbendazole 50mg

A white powder

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 (eelworm)
Trichuris suis (whipworm)
Metastrongylus apri (Lungworm)

5. CONTRAINDICATIONS

Do not use in cases of known hypersensitivity to the active substance, other benzimidazoles 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 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 use by adding 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 1g of product per 10kg bodyweight or 5g of product per 50 kg bodyweight or 20g of product per 200 kg bodyweight.

To ensure the correct dosage and to avoid possible under-dosing, the bodyweight and the amount of product to be administered should be determined as accurately as possible. To accurately measure the correct amount of product, a suitably calibrated weighing scale should be used.
The recommended amount of veterinary medicinal product should be added to a small quantity of the estimated daily amount of food for each individual animal in a bucket or a similar container and should be mixed thoroughly prior to being offered for immediate consumption.
Medicated feed should be freshly prepared before administration.
Part-consumed feed must be disposed of with other waste feed and not given to other animals.
Dosing table:

Pig Bodyweight (kg)	Amount (g) of product
50 kg	5g
100 kg	10g
150 kg	15g
200 kg	20g

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

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.

Store in a dry place.
Store in the original container in order to protect from light.
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

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:

None.

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.

This product may cause hypersensitivity (allergy) reactions. People with known hypersensitivity to fenbendazole should avoid contact with the veterinary medicinal product.

Avoid skin contact when handling 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, 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.
In case of skin and/or eye contact, immediately rinse with plenty of water.
Wash hands after use.

Accidental ingestion of the product should be avoided. In the event of accidental ingestion, rinse mouth with plenty of clean water and seek medical advice.”

Other Precautions

The veterinary medicinal product should not be allowed to enter surface waters as it has harmful effects on fish and other aquatic organisms.

Pregnancy:

The product can be used in pregnant and lactating sows.

Interaction with other medicinal products and other forms of interaction:

Exacerbation of paracetamol hepatotoxicity by fenbendazole cannot be excluded.

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 fish and other aquatic organisms.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2021

15. OTHER INFORMATION

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

200g and 1kg bag composed of clear low density polyethylene (LDPE) laminated with metallised polyester.
1 kg bag composed of clear low density polyethylene (LDPE).

5 x 200g LDPE laminated bags in a cardboard box
1 kg LDPE laminated bag
1 kg LDPE bag inside a white polypropylene container.

Not all pack types may be marketed.

For any information about this veterinary medicinal product, please contact the local representative holder.

Approved: 09/03/21