ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pigfen 40 mg/g premix for medicated feeding stuff for pigs
Fenbendazole

2. STATEMENT OF ACTIVE SUBSTANCES

Per gram:
Fenbendazole 40 mg

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff.

4. PACKAGE SIZE

1 kg
2 kg
5 kg
20 kg

5. TARGET SPECIES

Pigs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

The product is suitable for herd medication of pigs. Administer at a dose rate of 5 mg fenbendazole per kg bodyweight.

May be administered to pigs either as a single dose of 5 mg/kg (migrating larval, intestinal larval and adult stages) or by divided dose of 0.72 mg/kg over 7 days (intestinal larval and adult stages) or 0.36 mg/kg over 14 days (intestinal larval and adult stages).

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Meat and offal: 4 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Exp:

Once opened use by….

Shelf-life after first opening: 3 months.

Shelf life after incorporation into meal or pelleted feed: 3 months.

11. SPECIAL STORAGE CONDITIONS

None.

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

For disposal read the 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

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 30282/4027

17. MANUFACTURER'S BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Pigfen 40 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:
Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium

Manufacturer responsible for batch release:
Biovet JSC
39 Petar Rakov Str
4550 Peshtera
Bulgaria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pigfen 40 mg/g premix for medicated feeding stuff for pigs
Fenbendazole

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

Per gram:

Fenbendazole 40 mg

Premix for medicated feeding stuff.
Off-white to light yellow granules.

4. INDICATION(S)

Treatment of pigs infected with *Ascaris suum* (adult, intestinal and migrating larval stages) susceptible to fenbendazole.

5. CONTRAINDICATIONS

Do not use in known cases of hypersensitivity to the active substance, other benzimidazoles or any of the excipients.

6. ADVERSE REACTIONS

None known.

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

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Pigs

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

Oral use. In-feed use.

The product is suitable for herd medication of pigs. Administer at a dose rate of 5 mg fenbendazole per kg bodyweight.

May be administered to pigs either as a single dose of 5 mg/kg (migrating larval, intestinal larval and adult stages) or by divided dose of 0.72 mg/kg over 7 days (intestinal larval and adult stages) or 0.36 mg/kg over 14 days (intestinal larval and adult stages).

Single dose treatment

Use the following formula to calculate how much product to add per tonne of feed:

$$\text{Kg Powder per tonne} = \frac{\text{Bodyweight (kg)}}{\text{(Daily feed intake (kg) x 8)}}$$

7 day treatment

The standard dose rate can be divided and administered in feed over 7 days. Use the following formula to calculate how much product to add per tonne of feed:

$$\text{Kg Powder per tonne} = \frac{\text{Bodyweight (kg)}}{\text{(Daily feed intake (kg) x 56)}}$$

14 day treatment

The standard dose rate can be divided and administered in feed over 14 days. Use the following formula to calculate how much product to add per tonne of feed:

$$\text{Kg Powder per tonne} = \frac{\text{Bodyweight (kg)}}{\text{(Daily feed intake (kg) x 112)}}$$

9. 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.

For incorporation into dry feed at the registered mill.

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

To ensure adequate distribution of the product in the final feed it is recommended to premix the product at a ratio of 1:10 with feed ingredients before blending into the final feed.

If the premix is used for supplementation of pelleted feed, the pelleting temperature should not exceed 85 °C.

Not to be mixed in liquid feed.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 4 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

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 container: 3 months.

Shelf life after incorporation into meal or pelleted feed: 3 months.

Medicated feed (mashed and pelleted): no special storage precautions.

12. SPECIAL WARNING(S)

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.
- Under dosing, 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, ananthelmintic belonging to another pharmacological class and having a different mode of action should be used.

The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient uptake of feed, animals should be treated parenterally.

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 veterinary medicinal product may be toxic to humans after ingestion.

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.

This product may cause eye irritation and skin sensitisation.

Avoid contact with skin and/or eyes.

When handling or mixing, care should be taken to avoid direct contact with the skin and eyes, and inhalation of dust, by wearing goggles, impervious gloves and a disposable half-mask respirator conforming to European Standard EN149 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.

Pregnancy and lactation:
The product can be safely administered to pregnant animals.

The safety of the veterinary medicinal product has not been established during lactation. Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Exacerbation of paracetamol hepatotoxicity by fenbendazole cannot be excluded.

Overdose:
Pigfen administered as a single 25 mg fenbendazole/kg dose for three consecutive days did not produce any clinically apparent adverse reactions in pigs. In addition, it has been shown that administration of non-formulated fenbendazole at a dose of 2000 mg/kg for 14 consecutive days was well tolerated in pigs.

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

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.
These measures should help to protect the environment.

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

August 2021

15. OTHER INFORMATION

The product is distributed in multiple-layer paper bag with internal aluminium/polyethylene layer and with sutured crimp of 20 kg, as well as in polyethylene/aluminium foil/polyethylene terephthalate zipper bag of 1, 2 and 5 kg.

Not all pack sizes may be marketed.

Approved: 17/09/21