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

2. STATEMENT OF ACTIVE SUBSTANCES

Per gram:
Fenbendazole 40 mg

3. PACKAGE SIZE

1 kg
2 kg
5 kg
20 kg

4. TARGET SPECIES

Pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use. In-feed use

The veterinary medicinal 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).

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 4 days

8. EXPIRY DATE

Exp {mm/yyyy}:
Once opened use by….
Shelf-life after first opening the immediate packaging: 3 months.
Shelf life after incorporation into meal or pelleted feed: 3 months.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

14. MARKETING AUTHORISATION NUMBERS

Vm 30282/3017

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

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

2. Composition

Each gram contains:

Active substance:
Fenbendazole 40 mg

Off-white to light yellow granules.

3. Target species

Pigs.

4. Indications for use

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

5. Contraindications

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

6. Special warnings

Special warnings:
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 veterinary medicinal 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.

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 safe use in the target species:
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 veterinary medicinal product should be avoided.

In case of accidental ingestion, rinse mouth with plenty of clean water and seek medical advice immediately and show the package leaflet or the label to the physician.

This veterinary medicinal 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.

Special precautions for the protection of the environment:
The veterinary medicinal product should not be allowed to enter surface waters as it has harmful effects on aquatic organisms.

Pregnancy and lactation:
The veterinary medicinal 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:
The veterinary medicinal product 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.

Special restrictions for use and special conditions for use:
This veterinary medicinal product is intended to be used for the preparation of medicated feed.

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

7. Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Oral use. In-feed use.

The veterinary medicinal 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 veterinary medicinal product to add per tonne of feed:

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

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 veterinary medicinal product to add per tonne of feed:

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

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 veterinary medicinal product to add per tonne of feed:

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

9. Advice on correct administration

To ensure a correct dosage, 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.

The intake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of fenbendazole may need to be adjusted accordingly.

For incorporation into dry feed at the registered mill.

A manufacturer who is approved to incorporate veterinary medicinal products, or premixtures containing such veterinary medicinal 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 veterinary medicinal product in the final feed it is recommended to premix the veterinary medicinal 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 periods

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 immediate packaging: 3 months.

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

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

12. Special precautions for disposal

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

The veterinary medicinal product should not enter water courses as fenbendazole may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection system. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 30282/3017

The veterinary medicinal 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.

15. Date on which the package leaflet was last revised

December 2023

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions
Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium
+32 3 292 83 05 or +32 3 288 18 49
pharmacovigilance@huvepharma.com

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

Local representatives and contact details to report suspected adverse reactions

Approved 04 May 2024