# 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 granules

## 2. STATEMENT OF ACTIVE SUBSTANCES

Per gram:
Fenbendazole 40 mg

## 3. PACKAGE SIZE

0.250 kg
0.500 kg
1 kg

## 4. TARGET SPECIES

Pigs.

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Oral use

May be administered to pigs using the following dosage regimens:

- Single dose of 5 mg fenbendazole (corresponding to 125 mg of the veterinary medicinal product) per kg bodyweight (migrating larval, intestinal larval and adult stages);
- 0.72 mg fenbendazole (corresponding to 18 mg of the veterinary medicinal product) per kg bodyweight per day for 7 consecutive days (intestinal larval and adult stages);
  0.36 mg fenbendazole (corresponding to 9 mg of the veterinary medicinal product) per kg bodyweight per day for 14 consecutive days (intestinal larval and adult stages)

## 7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 4 days

## 8. EXPIRY DATE

Exp: {mm/yyyy}
Shelf life after first opening the immediate packaging: 3 months.
Once opened use by….

## 9. SPECIAL STORAGE PRECAUTIONS

After first opening of the immediate packaging: do not store above 25°C.

## 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 30282/3016

## 15. BATCH NUMBER

Lot {number}

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

Pigfen 40 mg/g granules for pigs

## 2. Composition

Each g 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.

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, 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.

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.

The veterinary medicinal product is only intended for the treatment of individual pigs on farms where a small number of pigs are to receive treatment.

May be administered to pigs using the following dosage regimens:

- Single dose of 5 mg fenbendazole (corresponding to 125 mg of the veterinary medicinal product) per kg bodyweight (migrating larval, intestinal larval and adult stages);
- 0.72 mg fenbendazole (corresponding to 18 mg of the veterinary medicinal product) per kg bodyweight per day for 7 consecutive days (intestinal larval and adult stages);
- 0.36 mg fenbendazole (corresponding to 9 mg of the veterinary medicinal product) per kg bodyweight per day for 14 consecutive days (intestinal larval and adult stages)

## 9. Advice on correct administration

To be mixed with a small quantity (20%) of the daily feed ration and administered prior to offering the remaining feed.

The treated feed must be prepared daily just before administration to the animals.

Pigs to be treated should be separated and treated individually.

To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended. 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.

Partly-consumed feed must be disposed of with other waste feed and not given to other animals.

## 10. Withdrawal periods

Meat and offal: 4 days

## 11. Special storage precautions

Keep out of the sight and reach of children.

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.
Veterinary medicinal product as packaged for sale: no special storage precautions.
Shelf life after first opening the immediate packaging: 3 months.
After first opening of the immediate packaging: do not store above 25°C.

## 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 30282/3016

The veterinary medicinal product is distributed in polyethylene/aluminium foil/polyethylene terephthalate zipper bags of 0.250 kg, 0.500 kg and 1 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