ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pigfen 200 mg/ml suspension for use in drinking water for pigs.
Fenbendazole

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:

Active substance:
Fenbendazole 200 mg

Excipients:
Sodium benzoate 3 mg

3. PHARMACEUTICAL FORM

Suspension for use in drinking water

4. PACKAGE SIZE

125 ml
1 L
2.5 L
5 L

5. TARGET SPECIES

Pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 4 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

Shelf life after first opening: 3 months. Once opened use by….
Medicated drinking water should be refreshed or replaced every 24 hours

11. SPECIAL STORAGE CONDITIONS

Product as packed for sales and after first opening: Do not freeze. Protect from frost.
Medicated water: Do not freeze.

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

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 N.V.
Uitbreidingstraat 80
2600 Antwerpen
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 30282/4038

17. MANUFACTURER'S BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Pigfen 200 mg/ml suspension for use in drinking water 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 N.V.
Uitbreidingstraat 80
2600 Antwerpen
Belgium

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pigfen 200 mg/ml suspension for use in drinking water for pigs.
Fenbendazole

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

Suspension for use in drinking water
Each ml of white to almost white suspension contains :

Active substance:
Fenbendazole 200 mg

Excipients:
Sodium benzoate 3 mg

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in known 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(S) AND METHOD OF ADMINISTRATION

For use in drinking water.

Shake well before use.

The dose is 2.5 mg fenbendazole per kg body weight per day (equivalent to 0.0125 ml Pigfen oral suspension per kg body weight per day). This dose has to be administered on 2 consecutive days. Dose calculation:
The required daily amount of product is calculated from the total estimated body weight (kg) of the entire group of pigs to be treated. Please use the following formula:
ml product/day = total estimated body weight (kg) of pigs to be treated x 0.0125 ml

9. ADVICE ON CORRECT ADMINISTRATION

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

Before allowing animals to have access to the medicated water, the water delivery system should be drained, if possible, and flushed with the medicated water to ensure accuracy of dosing. This procedure may need to be performed on all treatment days.

For each treatment day the medicated water needs to be freshly prepared.

Follow the instructions described below to prepare the medicated water. Use a sufficiently accurate commercially available measuring device.

For use in medication tank:
Add the calculated amount of product to the volume of drinking water usually consumed by the animals over 6 hours. Stir until content in the medication tank is visibly homogeneous. The medicated water appears hazy. No further stirring during administration is necessary.

For use in dosing pump:
Add the calculated amount of product to the unmedicated water in the stock suspension container of the dosing pump. The volume of unmedicated water in the stock suspension container has to be calculated taking into account the preset injection rate of the dosing pump and the volume of drinking water usually consumed by the animals over 6 hours. Stir until content in the stock suspension container is visibly homogeneous. The medicated water appears hazy.

During treatment all animals must have solely but unrestricted access to the medicated water.
During treatment, after complete consumption of the medicated water, animals must be allowed access to un-medicated drinking water as soon as possible.
Ensure that the total amount of medicated water offered is consumed.

10. WITHDRAWAL PERIOD

Meat and offal: 4 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Product as packed for sales and after first opening: Do not freeze. Protect from frost
Medicated water: Do not freeze.
After first opening: there are no special restrictions on storage conditions.

After reconstitution: there are no special restrictions on storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the bottle after “EXP”. The expiry date refers to the last day of that month.

Shelf life after first opening of the immediate packaging: 3 months
Shelf life after reconstitution in drinking water: 24 hours.

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, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

Special precautions for use
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.

This product may cause eye irritation.

Contact with the skin and the eyes or accidental ingestion of the product should be avoided.

Do not smoke, eat or drink when handling the veterinary medicinal product.

Wear goggles and impervious gloves to avoid direct skin and eye contact with the product when handling or preparing medicated drinking water.

In the event of accidental ingestion, rinse mouth with plenty of clean water and seek medical advice. In the event of accidental contact with the skin or eyes, rinse with plenty of clean water and seek medical advice.

Wash hands after use.

Use during pregnancy, lactation or lay
Administration of fenbendazole (500 mg/kg) to sows between days 8 and 33 of pregnancy produced no foetal effects. The safety of the product has not been established during lactation. Use 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 (symptoms, emergency procedures, antidotes), if necessary
No undesirable effects have been observed in pigs at up to 5 times the recommended dose.

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

April 2021

15. OTHER INFORMATION

White cylindrical High Density Polyethylene (HDPE) bottle with white polypropylene (PP) screw tamper-evident closure of 125 ml and 1 litre; white rectangular HDPE bottle of 1 litre with vertically see-through bar with an LDPE insert closed with white PP tamper- evident screw cap with a LDPE sealing disk.White HDPE canisters with white HDPE ribbed tamper-evident screw cap of 2.5 litres and 5 litres.

Not all pack sizes may be marketed.