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.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:
Fenbendazole 200 mg

3. PACKAGE SIZE

125 ml
1 L
2.5 L
5 L

4. TARGET SPECIES

Pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For use in drinking water.

7. WITHDRAWAL PERIODS

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….

Once diluted use within 24 hours.

9. SPECIAL STORAGE PRECAUTIONS

Veterinary medicinal product as packaged for sales and after first opening: Do not freeze. Protect from frost. Medicated water: Do not freeze.

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

14. MARKETING AUTHORISATION NUMBER

Vm 30282/5016

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE [Distribution category]

POM-V Veterinary medicinal product subject to prescription.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Each ml contains :

Active substance:
Fenbendazole 200 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Sodium benzoate (E211)	3 mg

White to almost white suspension.

3. TARGET SPECIES

Pigs.

4. INDICATIONS FOR USE

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

5. CONTRAINDICATIONS

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

6. 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 for 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 veterinary medicinal product may cause eye irritation.
Contact with the skin and the eyes or accidental ingestion of the veterinary medicinal product should be avoided.
Do not smoke, eat or drink when handling the veterinary medicinal product.
Wear goggles and impervious gloves to avoid directskin and eye contact with the product when handling or preparing medicated drinking water.
In case 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 immediately and show the package leaflet or the label to the physician.
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:
Administration of fenbendazole (500 mg/kg) to sows between days 8 and 33 of pregnancy produced no foetal effects. 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:
No undesirable effects have been observed in pigs at up to 5 times the recommended dose.

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:

E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

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

In drinking water use.

Shake well before use.

The dose is 2.5 mg fenbendazole per kg body weight per day (equivalent to 0.0125 ml veterinary medicinal product per kg body weight per day). This dose has to be administered on 2 consecutive days. Dose calculation:
Based on the recommended dose and the number and weight of animals to be treated, the exact daily dose of the veterinary medicinal product should be calculated according to the following formula:

ml veterinary medicinal product/day = total estimated body weight (kg) of pigs to be treated x 0.0125 ml

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9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage, 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 veterinary medicinal 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 veterinary medicinal 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 PERIODS

Meat and offal: 4 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Veterinary medicinal product as packaged for sales and after first opening: Do not freeze. Protect from frost
Medicated water: Do not freeze.
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 the immediate packaging: 3 months
Shelf life after dilution according to directions: 24 hours.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
The veterinary medicinal product should not enter water courses as fenbendazole may be dangerous for fish and other aquatic organisms.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 30282/5016

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.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

December 2023

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>

17. OTHER INFORMATION

Approved 04 May 2024