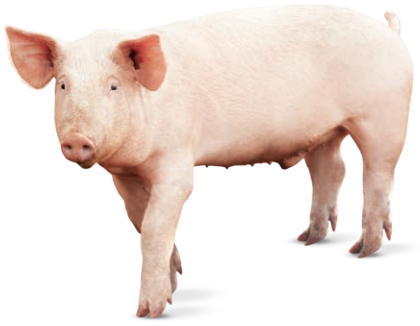
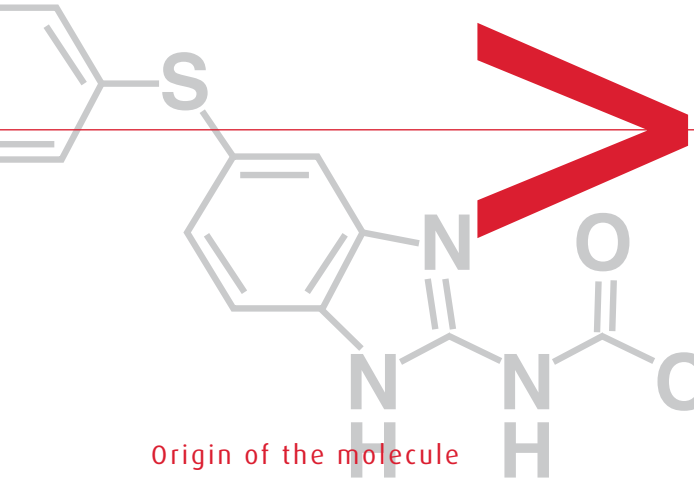
Pigfen®

200 mg fenbendazole/ ml
Suspension for use in drinking water for pigs



Easy deworming

HUVEPHARMA®
We add performance to your business



Origin of the molecule

Fenbendazole is an anthelmintic belonging to the benzimidazole-carbamate group. The benzimidazoles were introduced into the animal health market primarily for the control of gastrointestinal nematodes. Their use quickly became widespread because they offered major advantages over previous medications in terms of spectrum, efficacy against immature stages and safety for the host animal. They did not cause a set-back due to drug toxicity and it was possible to demonstrate the economic advantage of strategic treatment, even under conditions of mild parasitism.

Activity

This molecule has a very broad spectrum anthelmintic activity against:

- ***Ascaris suum***: by far the most economically important nematode with a migrating larval stage
- ***Oesophagostomum dentatum***: the nodular worm associated with 'thin sow syndrome'
- ***Trichuris suis***: the whipworm residing in the colon and producing colitis in growing pigs
- ***Stephanurus dentatus***: the pig kidney worm
- ***Hyostrongylus rubidus***: the stomach worm particularly seen in outdoor kept sows
- ***Strongyloides***: rarely reported nematode, capable of passing through the milk to infest piglets
- ***Metastrongylus***: the pig lungworm requiring an earthworm as an intermediate host
- ***Trichinella spiralis***: an uncommon helminth with important zoonotic implications.

Pharmacodynamics

Fenbendazole acts by binding to beta-tubulin, thereby inhibiting the polymerisation of tubulin to microtubules and subsequently interfering with energy metabolism. The molecule is effective at killing all adult , larval stages and eggs of worm parasites.

Resistance

Resistance of pig nematodes to fenbendazole is not widespread nor viewed to be a major problem.

Indications for use

Pigs

Pigfen® 200 mg/ ml suspension for use in drinking water for pigs is indicated for the treatment of pigs infected with *Ascaris suum* (adult, intestinal and migrating larval stages).

Formulation: Nanosuspension

Pigfen® 200 mg/ ml suspension is developed by an innovative nanosuspension technology, ensuring all particles have a very small particle size in the nanometer range.

Benefits

- **Efficacy**
  - Homogenous suspension
    - Independent of water quality
    - In different kinds of administration systems for water medication
  - Higher bio-availability and stability
- **Safety**
  - No sedimentation
  - No obstructions
  - No risk of residues in pipelines
- **Convenience**
  - No additional steps needed
  - Very short preparation time

Pigfen® nanosuspension

Homogeneity
Small particles

Other suspensions

Disadvantages
-Predilution step
-Additional stirring

Precipitation
Bigger particles

EGGS IN THE ENVIRONMENT

1

DAY 0

- Very high resistance
  - Sticky outer coating
  - Resistant to all kind of infections
  - Survive for 5 years
- Embryonating phase : L1 → L2 → L3
  - Intensity depends on humidity and temperature
  - Takes 14 to 40 days

digestive mucosa
passage in the mesenterial veins

PREPATENT PERIOD

A. SUUM

6 weeks

bronchi, trachea, pharynx

SMALL INTESTINES

4

DAY 10-14

- L4 → L5 → adults : minimum 35 days after infection
- Female adults produce up to 200.000 eggs a day
- Intermittent excretion
- High infection pressure in very short time

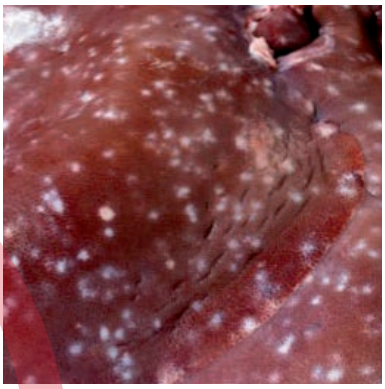
Diagnostics

Ascaris suum infections are omnipresent but their presence is often underestimated due to their subclinical nature. Diagnosis can be based upon different diagnostic tools which should be interpreted correctly.

Diagnostic tools	Pro	Contra
White spots on the liver	Recent larval migration	Livers heal within 6 weeks Not related to the degree of infection
Eggs per gram of faeces count	Related to adult worms	Not representative
Serodiagnostic test	Reflects the total degree of infection High sensitivity and specificity	

LIVER

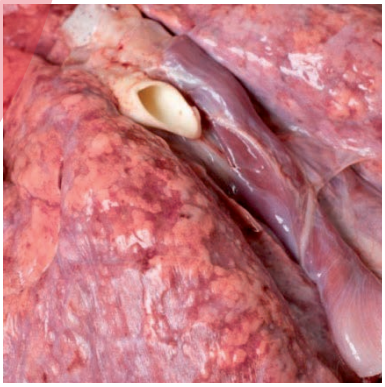
DAY 1-2



2

- L3 larvae hatch the eggs in caecum and upper colon
- Migration of L3 causes hepatitis
- White spots

LUNGS



3

DAY 4-5

- L3 → L4
- Migration causes haemorraghia
- Triggers Porcine Respiratory Disease Complex

Pigfen®

Contra-indications

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

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 in animals

None

Special precautions to be taken by the person administering the 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.

Adverse reactions (frequency and seriousness)

None known

Use during 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 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.

Major incompatibilities

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

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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.

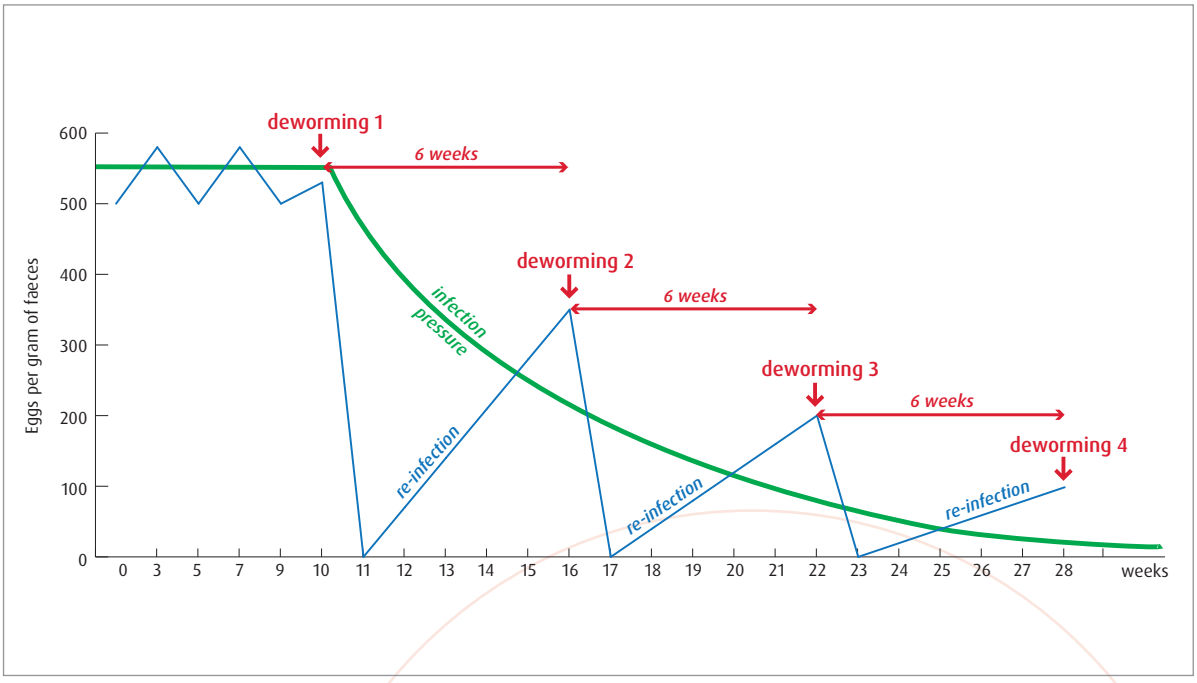


Fig.: Deworming strategy for fatteners

Deworming strategy: every 6 weeks

1. Improves pig performance significantly
2. High return on investment
3. Based on prepatent period of *Ascaris suum*
4. Several consecutive treatments are needed

Economical benefits of a deworming strategy:

1. Improved technical performances

▪ FCR (Feed Conversion Rate)	5 % ↙	**3.6 €**
▪ ADG (Average Daily weight Gain)	5 % ↗	**2.1 €**
▪ Mortality and dropouts	25 % ↙	**1.6 €**
▪ Better classification of carcasses	3 % ↗	**0.1 €**

2. Less condemnation of livers

▪ Cost of rejected liver	**1.5 €**

3. Reduction of medication cost **0.4 €**

- Respiratory and intestinal infections ↙
- Immune response ↗
- Efficacy of vaccinations ↗

Resulting in > 9 € income gain / fattener

> 9 €

Pigfen® 200 mg/ ml suspension

Product specifications

- 1 ml contains 200 mg fenbendazole
- White to almost white suspension

Dosing

- For use in drinking water
- In medication tanks and dosing pumps
- Stir until content is visibly homogeneous
- No further stirring during administration is necessary

Fenbendazole/ kg bodyweight		
Daily dose	2.5 mg	during 2 consecutive days
Total dose	5 mg	

Pigfen® oral suspension/ 1000 kg bodyweight		
Daily dose	12.5 ml	during 2 consecutive days
Total dose	25 ml	

Packaging	Total bodyweight
125 ml	5.000 kg
1 l	40.000 kg
2.5 l	100.000 kg
5 l	200.000 kg

Withdrawal period

Meat and offal: **4 days**

Shelf life and storage

Shelf life

- Of the veterinary medicinal product as packaged for sale: 30 months
- After first opening the immediate packaging: 3 months.
- Of the medicated drinking water: 24 hours.

Protect product as packed for sale and after first opening from frost. Do not freeze medicated water.

Overdose

No undesirable effects have been observed in pigs at up to 5 times the recommended dose.

Packaging

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.

Deworming strategy

- Fatteners: **Every 6 weeks** from 10 weeks of age onwards
- Sows: Every 3 months
- Gilts: On arrival and repeat treatments every 6 weeks

*Used references can be obtained upon demand.
*Pigfen® oral suspension brochure follows the authorized EU SPC (available on request).
*Indications listed above are not necessarily authorized in all countries.
*Please consult the local label for exact indications and posology.
*Use medicines responsibly.
*POM-V
*VM 30282/4038

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