SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Panacur 4 % Veterinary

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g powder contains:
Pharmaceutically active ingredient:
Fenbendazole 40 mg

Other ingredients:
See “List of excipients” in paragraph 6.1. for a complete list of excipients.

3. PHARMACEUTICAL FORM

Powder for the preparation of medicated feed
White to grayish powder.

4. CLINICAL DATA

4.1 Target species

Pigs

4.2 Indications for use, specifying target species

For the treatment of infestation of pigs with gastrointestinal worms in their immature and mature stages, kidney worms and/or lungworms and, for example:
red stomach worms, nodular worms, roundworms, whipworms, kidney worms and lungworms.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings

None.

4.5 Special precautions for use

Special precautions for use on animals
Not applicable.

Special precautions for the user
Not applicable.

4.6 Side effects (frequency and severity)

None known.

Reporting suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form
https://sideeffects.health.gov.il

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

4.8 Interactions with other medicines and other interactions

None known.

4.9 Dosage and use

The preparation can be offered with the usual feed and consumed separately or used to prepare a medicated feed (mixed with industrial feed or an appropriate commercially available compound feed).

Unless otherwise prescribed, adhere exactly to the dose.
Recommended dose: 5 mg Fenbendazole (FBZ)/kg body weight (BW)
For infestation with Stephanurus dentatus (swine kidney worm): 10 mg FBZ/kg BW

1. Single treatment with the therapeutic dose

Single treatment
A graduated measuring beaker is included for 500 g and 2.5 kg doses.

Mass treatment
In order to prepare a medicated feed, the therapeutic dose (5 mg Fenbendazole per kg BW) should be mixed into the daily ration.
For example, the following procedure should be used:

Animal species	Feed consumption	Powder per tonne of compound feed
Fattening pigs Approx. 20 kg BW	1 kg/day/animal	2.5 kg
Sows Approx. 200 kg BW	2 kg/day/animal (basic ration)	12.5 kg

For infections with kidney worms, the dose should be doubled (10 mg Fenbendazole/ kg/BW).
For attacks with whip worms and/or lungworms, treatment should be administered according the procedure described in Section 2.

2. Distribute the therapeutic dose across 5-15 days
When preparing a medicated feed, the therapeutic dose (5 mg Fenbendazole per kg BW) should be mixed into the compound feed ration intended for 5-15 days.

For example, the following procedure should be used:

Animal species	Treatment duration	Feed consumption	Powder per tonne of compound feed
Fattening pigs approx. 20 kg BW	5 days 10 days 15 days	1 kg/Day/Animal	0.5 kg 0.25 kg 0.17 kg
Sows approx. 200 kg BW	5 days 10 days 15 days	2 kg/day/animal (Basic ration)	2.5 kg 1.25 kg 0.83 kg

In order to prepare pre-mixes (2 kg/t feed), wheat middlings are recommended.

The powder is odourless, tasteless and accepted by the animals.

The preparation can also be administered to animals that are seriously ill, pregnant or generally in poor condition.

Dietary measures are not required before or after treatment. Repeat the treatment after reinfection.

4.10 Overdose (symptoms, procedures in case of emergency, antidotes), if necessary

No information

4.11 Withdrawal period(s)

Edible tissue: 7 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Benzimidazole and related substances
ATCvet-Code: QP52AC13

5.1 Pharmacodynamic properties

The basic mechanism behind the anthelmintic effect of Fenbendazole is that it inhibits the polymerisation of tubulin to form microtubules. As a result, important structural characteristics of the helminth cell are impaired, such as formation of the cytoskeleton, spindle formation during mitosis, as well as the intake and intracellular transport of nutrients and metabolic substrates. This leads to the exhaustion of energy reserves so that the parasite subsequently dies and is expelled after 2-3 days.

Fenbendazole has an ovicide effect, which occurs after approx. 8 hours due to the inhibition of spindle formation and metabolic disorders during embryogenesis.

Fenbendazole is highly effective against adult and immature gastrointestinal nematodes and lungworms, as well as larvae in their inhibited and histotrophic stages.

In addition, Fenbendazole is effective against different types of tapeworm.

5.2 Pharmacokinetic information

Some of the Fenbendazole is reabsorbed after oral application before most of the substance is metabolised in the liver. Reabsorption takes place faster in single stomach animals than in ruminants. A sulfoxide and a sulfone metabolite are formed, which are the main metabolites.

The half-life period of Fenbendazole in the serum is 10 hours after the recommended dose is administered orally to the pig. Fenbendazole and its metabolites are distributed throughout the entire organism, with high concentrations in the liver. The excretion of unchanged and metabolised Fenbendazole takes place predominantly (> 90%) in the faeces and, to a lesser extent, in the urine and milk.

6. PHARMACEUTICAL INFORMATION

6.1 List of other excipients

Lactose monohydrate, Calcium carbonate, Maize starch, Colloidal anhydrous silica

6.2 Incompatibilities

None known.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store below 25ºC.
Store in dry place.
Protect from light.
Do not store in refrigerator or freezer.
Keep in the original packaging.

6.5 Nature and characteristics of the primary packaging

Package size:
2.5 kg

2.5 kg commercial form: White coloured Polypropylene Plastic bucket with low density polyethylene (LDPE) inner bag and polypropylene measuring beaker

6.6 Special precautions for the disposal of unused veterinary medicinal products and waste materials derived from their use

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of as toxic waste, do not throw to sewer.

7. MANUFACTURER

Intervet GesmbH
Siemensstrasse 107,

1210 Vienna, Austria

8. LICENSE HOLDER

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9. LICENSE NUMBER

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