SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Zerofen vet. 40 mg/g oral powder for pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance:

Fenbendazole 40 mg

Excipient:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Lactose monohydrate	960 mg

A white to off-white powder.

3 CLINICAL INFORMATION

3.1 Target species

Pigs from the age of weaning

3.2 Indications for use for each target species

The veterinary medicinal product is a broad spectrum anthelmintic for the treatment of pigs infected with nematodes of the gastro-intestinal tract:

Red stomach worms: *Hyostrongylus rubidus* (mature and immature forms)
Nodular worms*:* *Oesophagostomum spp.* (mature and immature forms)
Eel worms: *Ascaris suum* (mature forms)

3.3 Contraindications

None known.

3.4 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.
  - Underdosing, 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Intolerance to lactose is seen in animals who lack the intestinal enzyme lactase, which can lead to diarrhoea, abdominal discomfort, distension and flatulence.

The frequent and repeated use of benzimidazoles can develop resistances.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

People with known hypersensitivity to Fenbendazole should avoid contact with the veterinary medicinal product.
Because of possible sensitisation and contact dermatitis, direct skin contact and inhalation should be avoided. When handling, suitable protective equipment such as rubber gloves and filtering masks should be used. Hands should be washed after handling the finished feed. veterinary medicinal product is harmful if swallowed.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

See Section 3.5.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Since benzimidazoles may possess embryotoxic effects restrictive use in the first stage of pregnancy is recommended.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.
The veterinary medicinal product should be administered orally, mixed with feed.
The normal dose rate is 5 mg of fenbendazole per kg bodyweight, given as a single dose, which corresponds to 1.2 g of powder per 10 kg of bodyweight.

Calibrated scales should be used in order to weigh accurate dosing amounts.
To ensure a correct dosage, body weight should be determined as accurately as possible.
For use in individual pigs on farms where only a small number of pigs are to receive the medicine.

The veterinary medicinal product should be mixed thoroughly to achieve a homogenous and stable mixture.

It has to be ensured that the calculated dose is completely taken up by the animals. Consideration must be given to pigs whose daily feed intake is reduced or restricted.

The veterinary medicinal product is not intended for medicated feed manufacturing. It should not be administered in the drinking water.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No known risks.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable

3.12 Withdrawal periods

Meat and offal: 3 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AC13

4.2 Pharmacodynamics

The veterinary medicinal product is a broad spectrum anthelmintic for the treatment of pigs infected with mature and immature forms of nematodes of the gastro-intestinal and respiratory tracts. It has an ovicidal effect in some genera of parasites. The active substance in the veterinary medicinal product is fenbendazole, which belongs to the group of benzimidazoles. Fenbendazole is a white, tasteless powder without smell, which is insoluble in water and insoluble or difficult to dissolve in conventional solvents. Fenbendazole has a broad safety margin and can be given to young animals.
The anthelmintic effect of fenbendazole is exercised by inhibition of the glucose uptake, as it binds to nematode tubulin, a protein necessary for the formation and viability of microtubules. This occurs primarily in the intestinal cells of the nematode, which leads to a ceased absorption of nutrients, especially glycogen, resulting in starvation of the parasite.
Structural differences have been showed to exist between tubulin from mammalian respectively helmintic sources. This explains why fenbendazole is toxic for the parasite but not for the host.

4.3 Pharmacokinetics

Fenbendazole exerts its main effect in the gastro-intestinal tract. Only approximately 30% of the dose is absorbed in pigs. After a dose of 5mg/kg bodyweight, maximal plasma concentration is achieved in 4.5-10 hours. Elimination half-life in plasma is approximately 10 hours in pigs. Elimination of fenbendazole takes place by >50% via faeces and by 30% via urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.

5.3 Special precautions for storage

Keep the container tightly closed. Keep in the original container.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is presented in pack sizes of 500 g, 1 kg, 2.5 kg, 5 kg and 10 kg, packed into LDPE bags in polypropylene containers.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.
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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORIZATION NUMBERS(S)

8. DATE OF FIRST AUTHORISATION

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

2025-01-17

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).