PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Zerofen vet. 40 mg/g oral powder for pigs

2. Composition

Each g contains:

Active Substance:

Fenbendazole 40 mg/g

Excipient:

Lactose Monohydrate 960 mg/g

A white to off-white powder

3. Target species

Pigs from the age of weaning

4. Indications for use

Zerofen vet. 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 stages)
Nodular worms; *Oesophagostomum spp*. (mature and immature stages)
Eel worms; *Ascaris suum* (mature stages)

5. Contraindications

None Known.

6. Special warnings

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.

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.

Pregnancy:

Since benzimidazoles may possess embryotoxic effects, restrictive use in the first stages of pregnancy is recommended.

7. Adverse events

Pigs:

See section 6.

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: {national system details}*[listed in* Appendix I*]*.

8. Dosage for each species, routes and method of administration

Zerofen vet. 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 bodyweight.

Calibrated scales should be used in order to weigh accurate dosing amounts.
To ensure administration of a correct dose, 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.

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.

9. Advice on correct administration

Zerofen vet. is not intended for medicated feed manufacturing. It should not be administered in the drinking water.

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

10. Withdrawal periods

Meat and offal: 3 days.

11. Special storage precautions

Keep out of the sight and reach of children.
Keep in the original container.
Keep the container tightly closed.
Do not use this veterinary medicinal product after the expiry date which is stated on the container after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes: 500 g, 1 kg, 2.5 kg, 5 kg and 10 kg.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

2025-01-17

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Chanelle Pharmaceuticals Manufacturing Ltd.,

Dublin Road,

Loughrea,

Co. Galway,

Ireland

Telephone: +353 (0)91 841788

vetpharmacoviggroup@chanellegroup.ie

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.