

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zerofen 222.2 mg/g Granules.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Fenbendazole 222.2 mg/g

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Lactose	-
Povidone 30	-
Sodium Lauryl Sulphate	-

White to grayish-white granules.

3. CLINICAL INFORMATION

3.1 Target Species

Dogs and cats.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for the treatment of immature and mature stages of nematodes of the gastro-intestinal and respiratory tracts of domestic dogs and cats. It also has an ovicidal effect and is indicated for the following:

For the treatment of gastrointestinal nematodes and cestodes of domestic dogs and cats affected with *Ascarid* spp., *Ancylostoma* spp., *Uncinaria* spp., *Trichuris* spp. and *Taenia* spp. Also, for the treatment of lungworm nematodes of domestic dogs affected with *Oslerus (Filaroides) osleri*, and domestic cats affected with *Aelurostrongylus abstrusus*.

For the treatment of pregnant bitches to reduce pre-natal infections with *Toxocara canis* and the transfer of *Toxocara canis* and *Ancylostoma caninum* to their pups via the milk.

3.3 Contraindications

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

None.

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

Direct contact with the skin should be kept to a minimum. Avoid the inhalation of dust. Wash hands after use.

3.6 Adverse events

None.

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 authorization 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:

Can be used during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

For oral administration only (sprinkled onto food).

For the routine treatment of adult dogs and cats: 100 mg/kg is recommended.

For the treatment of weaned puppies and kittens: 50 mg/kg daily for three days is recommended.

For the control of lungworm, *Oslerus (Filaroides) osleri*, in dogs: 50 mg fenbendazole per kg per day for 7 days. A repeat course of treatment may be required in some cases.

For the control of lungworm, *Aelurostrongylus abstrusus*, in cats: 20 mg fenbendazole/kg per day for five days.

For the treatment of pregnant bitches: daily dosage of 25 mg fenbendazole/kg from day 40 of pregnancy continuously to 2 days post-whelping.

For the treatment of clinical worm infestations in adult dogs and cats: administer 1g of the veterinary medicinal product per 4.4 kg (10 lbs) bodyweight daily for 3 consecutive days (= 50 mg fenbendazole per kg bodyweight daily for 3 days).

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

Not applicable.

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

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AC13

4.2 Pharmacodynamics

The veterinary medicinal product contains fenbendazole which is a member of the benzimidazole family of anthelmintics and has been in veterinary use for a number of years. Fenbendazole acts against parasites by disrupting the formation of microtubules by binding to tubulin in parasitic intestinal cells thereby preventing the absorption of glucose, such that parasites are gradually starved to death. Fenbendazole displays preference for parasitic as opposed to mammalian tubulin. This appears to be due to the fact that the formation of the parasitic tubulin-fenbendazole complex is more favourable kinetically under physiological conditions than the mammalian complex.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2. Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

Store in a dry place.

Do not store above 25°C.

5.4 Nature and composition of immediate packaging

Foil paper sachets composed of 45 or 50 gsm paper/10 gsm polyethylene/8 um foil/25 gsm polyethylene. The veterinary medicinal product is packed in 1 g, 2 g, 3 g, 4 g and 5 g sachets. Sachets containing 1 g, 2 g and 4 g are available in the following presentations into carton:

100 x 1 g

120 x 1 g

70 x 2 g

120 x 2 g

4 x 4 g

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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 AUTHORISATION NUMBER(S)

VPA10987/140/001

8. DATE OF FIRST AUTHORISATION

15 March 1996

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

06 February 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

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