1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zerofen 100 mg/ml Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

Active Substance:
Fenbendazole 100 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl Parahydroxybenzoate	2 mg
Propyl Parahydroxybenzoate	0.2 mg
Amaranth (E123)	0.015 mg
Citric Acid Monohydrate	
Sodium citrate	
Xanthan Gum	
Povidone	
Polysorbate	
Propylene Glycol	
Simethicone emulsion	
Purified Water	

A pale pink smooth suspension.

3. CLINICAL INFORMATION

3.1 Target Species

Cattle.

3.2 Indications for use for each target species

This veterinary medicinal product is a broad spectrum anthelmintic for the control of mature and developing immature forms of the following major species of roundworm in cattle. In cattle it is effective against the following parasites:

Gastro-intestinal roundworms:
Ostertagia
Cooperia
Trichostrongylus
Nematodirus
Haemonchus
Oesophagostomum
Bunostomum
Strongyloides and
Trichuris species

Lungworms:
Dictyocaulus viviparus

It is usually effective against inhibited larvae of Ostertagia species in cattle. This veterinary medicinal product has an ovicidal effect on nematode eggs.

3.3 Contraindications

None.

3.4 Special warnings

As with other anthelmintics, veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control and reduce the likelihood of anthelmintic resistance developing. If the product does not achieve the desired clinical effect, other diseases, nutritional disturbances or anthelmintic resistance may be involved.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Shake container before use.

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

Direct contact with skin should be kept to a minimum. Personal protective equipment consisting of impermeable rubber gloves should be worn when handling the veterinary medicinal product. Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

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 the national competent authority via the national reporting system. See the label for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Cattle:
Given as an oral drench at the rate of 7.5 mg fenbendazole per kg bodyweight (approximately 1 ml per 13 kg bodyweight).

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

Meat: 14 days.
Milk: 96 days.

4 PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP52AC13.

4.2 Pharmacodynamics

The veterinary medicinal product is a broad spectrum anthelmintic containing fenbendazole 100 mg/ml. Benzimidazoles bind to nematode tubulin, a protein necessary for the formation and viability of microtubules. This occurs primarily in absorptive intestinal cells resulting in a complete absence of microtubules in the intestinal cells of the nematode, which means that these cells cannot absorb nutrients, a consequent reduction in glycogen and effective starvation of the parasites. Structural differences have been shown to exist between tubulin from mammalian and helminth sources, thus resulting in the preferential toxicity of fenbendazole to the helminth and not to the host. Benzimidazoles have also been shown to inhibit the fumarate reductase system of helminths and impair energy production.

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

Do not freeze. Store at room temperature.

5.4 Nature and composition of immediate packaging

The product is presented in 0.5 L, 1 L, 2.5 L, 5 L and 10 L containers composed of high density polyethylene with polypropylene closures.

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.

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)

VPA 10987/017/001

8. DATE OF FIRST AUTHORISATION

04 January 2006

10 DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

29 August 2024

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).