1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zerofen 25 mg/ml Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:
Active Substance:

Fenbendazole 25 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 (E218)	2 mg
Propyl Parahydroxybenzoate (E216)	0.2 mg
Amaranth (E123)	0.015 mg
Citric Acid Monohydrate	-
Sodium Citrate	-
Xanthan gum	-
Povidone 90	-
Polysorbate 20	-
Propylene glycol Simethicone Emulsion	-
Purified Water	-

A pale pink smooth suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and sheep.

3.2 Indications for use for each target species

The veterinary medicinal product is a broad spectrum anthelmintic for the control of mature and developing immature forms of the major species of roundworms in sheep and cattle.
In sheep it is effective against benzimidazole susceptible strains of the following parasites:

Gastro-intestinal roundworms
Ostertagia spp.
Haemonchus spp.

Trichostrongylus spp.
Nematodirus spp.
Cooperia spp.
Oesophagostomum spp.
Chabertia spp.
Bunostomum spp.
Strongyloides spp.

Lungworms

Dictyocaulus filaria.

In cattle it is effective against the following parasites:

Gastro-intestinal roundworms

Ostertagia spp.
Cooperia spp.
Trichostrongylus spp.
Nematodirus spp.
Haemonchus spp.
Oesophagostomum spp.
Bunostomum spp.
Strongyloides spp.
Trichuris spp.

Lungworms

Dictyocaulus viviparus.

It is usually effective for the control of tapeworms, *Moniezia* spp., in sheep. The product may be useful for the control of *Trichuris* in sheep. It is usually effective against inhibited larvae.

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.

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 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:
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. Wear suitable protective clothing including impermeable rubber gloves. 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 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 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

To ensure a correct dosage, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.
If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.

Sheep:

Give as an oral drench at the rate of 5 mg fenbendazole per kg bodyweight. (1 ml per 5 kg bodyweight).

Cattle:

Give as an oral drench at the rate of 7.5 mg fenbendazole per kg bodyweight (3 ml per 10 kg bodyweight).

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

None known.

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

Sheep:
Meat and offal: 21 days.
Milk: Not authorised for use in animals producing milk for human consumption.

Cattle:
Meat and offal: 14 days.
Milk: 96 hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:
QP52AC13.

4.2 Pharmacodynamics

The veterinary medicinal product is a broad spectrum anthelmintic containing fenbendazole 25mg/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.

4.3 Pharmacokinetics

Fenbendazole is only partly absorbed after oral administration and is then metabolised in the liver. The half-life of Fenbendazole in serum after oral application of the recommended dose in cattle is about 10-18 hours and in sheep 21- 33 hours. Fenbendazole and its metabolites are distributed throughout the body and high concentrations can be found in the liver. The elimination of Fenbendazole and its metabolites occurs primarily via the faeces (>90%) and to a small extent in the urine and milk. Fenbendazole is metabolised to its sulfoxide then to sulphone and amines.

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 store above 25ºC. Do not freeze.

5.4 Nature and composition of immediate packaging

A suspension contained in 1 L, 2.5 L, 5 L and 10 L high density polythene containers 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 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.
This veterinary medicinal product should not enter water courses as {INN/active substance(s)} may be dangerous for fish and other aquatic organisms.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10987/017/002

8. DATE OF FIRST AUTHORISATION

05/08/1992

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

13/08/2024

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).