Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Zerofen 2.5% Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:		
Fenbendazole	2.5	% w/v
Excipients:		
Methyl Parahydroxybenzoate (E218)	0.2	% w/v
Propyl Parahydroxybenzoate (E216)	0.02	% w/v
Amaranth (E123)	0.0015	% w/v

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension
A pale pink smooth suspension

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and sheep.

4.2 Indications for use, specifying the target species

Zerofen 2.5% 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 sp.
Haemonchus sp.
Trichostrongylus sp.
Nematodirus sp.
Cooperia sp.
Oesophagostomum sp.
Chabertia sp.
Bunostomum sp.
Strongyloides sp.

Lungworms

Dictyocaulus filaria.

In cattle it is effective against the following parasites:

Gastro-intestinal roundworms

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

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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

Shake container before use.

Special Precautions to be taken by the Person Administering the 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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Zerofen 2.5% can be safely used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

To ensure administration of a correct dose, 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).

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Not applicable.

4.11 Withdrawal Period(s)

Sheep:
Edible tissues from slaughtered animals: 21 days.
Milk: Not for use in sheep producing milk for human consumption.

Cattle:
Edible tissues from slaughtered animals: 14 days.
Milk: 96 hours.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics; Benzimidazoles and related substances; Fenbendazole.
ATCvet Code: QP52AC13.

5.1 Pharmacodynamic properties

Zerofen 2.5% 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.

5.2 Pharmacokinetic properties

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)
Amaranth (E123)
Citric Acid Monohydrate
Sodium Citrate
Xanthan gum
Povidone 90
Polysorbate 20
Propylene glycol
Simethicone Emulsion
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not store above 25^{o}C.
Do not freeze.

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Do not contaminate ponds, waterways or ditches with product or used containers.
Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10987/017/002

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

4th August 2007

10 DATE OF REVISION OF THE TEXT

19th November 2009