Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Zerofen 10% Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances:

Fenbendazole	10	% w/v

Excipients:

Methyl Parahydroxybenzoate	0.2	% w/v
Propyl Parahydroxybenzoate	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.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

Zerofen 10% 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. Zerofen 10% has an ovicidal effect on nematode eggs.

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.

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 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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Zerofen 10% can be safely used at the recommended dose rate 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

Assess bodyweight as accurately as possible before calculating the dosage.

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

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

Not applicable.

4.11 Withdrawal Period(s)

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 14 days from the last treatment. Milk for human consumption must not be taken during treatment. Milk for human consumption may be taken from cows only after 96 hours from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Zerofen 10% is a broad spectrum anthelmintic containing fenbendazole 100mg/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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Amaranth
Citric Acid Monohydrate
Sodium citrate
Xanthan Gum
Povidone
Polysorbate
Propylene Glycol
Simethicone emulsion
Purified Water.

6.2 Incompatibilities

None.

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 freeze.

6.5 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 high density polyethylene closures.

Not all pack sizes may be marketed.

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

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

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10987/17/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

4th January 2006

10 DATE OF REVISION OF THE TEXT

November 2009

May 2013