SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zerofen Worm Drench 10% w/v oral suspension for Sheep and Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:
Fenbendazole 10 %w/v

Excipient(s):
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 pH 6 ± 0.5 suspension

4. CLINICAL PARTICULARS

4.1 Target species

Sheep and Cattle

4.2 Indications for use, specifying the target species

A broad spectrum anthelmintic for the control of mature and developing immature forms of the following major species of roundworm in sheep and cattle. In sheep it is effective against benzimidazole susceptible strains of the following parasites:

Gastro-intestinal roundworms: *Ostertagia, Haemonchus, Trichostrongylus, Nematodirus, Cooperia, Oesophagostomum, Chabertia, Bunostomum* and *Strongyloides* species.
Lungworms: *Dictyocaulus filaria.*
It is usually effective for the control of tapeworms, *Moniezia* spp, in sheep.
May be useful for the control of *Trichuris* in sheep.

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.
Has an ovicidal effect on nematode eggs.

4.3 Contraindications

None known

4.4 Special warnings <for each target species>

Care should be taken to avoid the following practices becaue 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 the 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.
Resistance to benzimidazoles has been reported in *Teladorsagia Haemonchus, Cooper and Trichostrongylus* species in small ruminants. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance for anthelmintics.

4.5 Special precautions for use

Shake container before use.

i. Special precautions for use in animals

Care should be taken not to injure the pharynx during administration.

ii. 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)

Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk dosing programmes should be discussed with your veterinary advisor.
Fenbendazole belongs to the Benzimidazole (1–BZ) class of anthelmintics.

4.7 Use during pregnancy, lactation or lay

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

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked
Cattle: Give as an oral drench at the rate of 7.5 mg fenbendazole per kg bodyweight (approximately 1 ml per 13 kg bodyweight).
Cattle over 400 kg should be given a further 5 ml for each additional 65 kg bodyweight.
Sheep: Give as an oral drench at the rate of 5 mg fenbendazole per kg bodyweight (approximately 1 ml per 20 kg bodyweight).
Sheep over 80 kg should be given a further 0.5 ml for each additional 10 kg bodyweight.

Do not mix with other products.

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

Benzimidazoles have a wide margin of safety.

4.11 Withdrawal period(s)

Animals must not be slaughtered for human consumption during treatment.
Sheep may be slaughtered for human consumption only after 21 days from the last 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 132 hours from the last treatment.
The product must not be used in sheep producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group, Benzimidazoles

ATCvet code: QP52AC13 Fenbendazole

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methylparahydroxybenzoate
Propylparahydroxybenzoate
Amaranth E123
Sodium Citrate Dihydrate
Citric acid monohydrate
Xanthan Gum
Povidone K 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 freeze.

6.5 Nature and composition of immediate packaging

High density polyethylene containers with high density polyethylene tamper-evident cap (screw-fit) and containing 1L, 2.5L, 5L or 10L of the product.
High density polyethylene flexipack containers with polypropylene tamper-evident cap (screw-fit) and containing 1L, 2.5L or 5L of the product.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

DANGEROUS to aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container. Any unused veterinary medicinal products or waste materials derived from such medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Chanelle Animal Health Ltd.
7 Rodney Street,
Liverpool L1 9HZ,
England.

8. MARKETING AUTHORISATION NUMBER(S)

Vm 11990/4001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16 July 1993

10 DATE OF REVISION OF THE TEXT

September 2010