Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Zerofen 4 % Premix for medicated feeding stuff

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Fenbendazole 4.0% w/w

Excipient:

Lactose Monohydrate 96% w/w

3 PHARMACEUTICAL FORM

A white to off white powder.
Premix for medicated feeding stuff.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs

4.2 Indications for use, specifying the target species

Zerofen 4% Powder is a broad spectrum anthelmintic for the treatment of pigs infected with mature and immature forms of nematodes of the gastro-intestinal tract:

Hyostrongylus rubidus (Red Stomach worm)
Oesophagostomum sp. (Nodular worms)
Ascaris suum (Eel worm)
Trichuris suis (Whipworm)

Zerofen has an ovicidal effect on nematode eggs.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

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

When preparing medicated feed, to ensure thorough dispersion, a pre-mix should be prepared first. Once mixed, this should then be incorporated with the remaining feed. The product can be incorporated into pelleted feed preconditioned with steam at a temperature not greater than 45^{o}C.

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

Feed mill operators – when handling or mixing, suitable dust extraction equipment and suitable protective equipment such as rubber gloves and filtering masks or 'Pureflo' helmet must be used.

Wash hands after handling medicated feedstuffs.
Direct contact with skin should be kept to a minimum.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Zerofen 4% Powder can be safely used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

Zerofen 4% Powder is administered orally, mixed with feed. The dose rate for administration is 5 mg fenbendazole per kg bodyweight (equivalent to approximately 3g Zerofen 4% Powder per 25 kg bodyweight). Zerofen 4% Powder may be administered to pigs either as:

(1)a single dose
(2.1)divided dosage over 7 days
(2.2)divided dosage over 14 days.

For the treatment of infections with *Trichuris* the dose of 5 mg/kg should be divided and spread over 7 days.

1) Single dose/One-day Treatment Mass medication

Use the following formula to calculate how much Zerofen 4% to add per tonne of feed:

*Kg Zerofen 4% = Bodyweight (kg)
Powder per tonne Daily feed intake (kg) x 8

The following table is provided as a guide:

Type of pig	Weight of pig (kg)	Average feed intake per day	Inclusion rate kg/tonne	No of pigs treated
Growing and finishing pigs	25 kg 50kg	1.25 kg 2.5 kg	2.5 kg/tonne 2.5 kg/tonne	800 400
Sows	150 kg 200 kg	2.0 kg 2.5 kg	9.375 kg/tonne 10.0 kg / tonne	500 400

2.1)Divided dosage / Mass medication over 7 consecutive days

Use the following formula to calculate how much Zerofen 4% to add per tonne of feed:

*Kg Zerofen 4% = Bodyweight (kg)
Powder per tonne Daily feed intake (kg) x 56

The following table is provided as a guide:

Type of pig	Weight of pig (kg)	Average feed intake per day	Inclusion rate g/tonne	No of pigs treated

Growing and finishing pigs	25 kg 50kg	1.25 kg 2.5 kg	360 g/tonne 360 g /tonne	114 57
Sows	150 kg 200 kg	2.0 kg 2.5 kg	1340 g/tonne 1429 g / tonne	70 57

2.2)Divided dosage / Mass medication over 14 consecutive days
Treatment may also be administered to sows over 14 days.
Use the following formula to calculate how much Zerofen 4% to add per tonne of feed:

*Kg Zerofen 4% = Bodyweight (kg)
Powder per tonne Daily feed intake (kg) x 112

The following table is provided as a guide:

Weight of pig (kg)	Average feed intake per day	Inclusion rate g/tonne	No of pigs treated
150 kg 200 kg	2.0 kg 2.5 kg	670 g/tonne 714 g / tonne	35 28

·To avoid underdosing, all inclusion rate calculations should be based on the heaviest pig in the group.

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. Pigs may be slaughtered for human consumption only after 14 days after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Zerofen 4% Powder is a broad spectrum anthelmintic for the treatment of pigs infected with mature and immature forms of nematodes of the gastro-intestinal tract. Each 1 g of Zerofen 4% Powder contains 0.04g of the active ingredient fenbendazole. Benzimidazoles bind to nematode tubulin, a protein necessary for the formulation 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. Fenbendazole may also inhibit energy production in helminths by inhibition of glucose uptake and glycogen breakdown.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after incorporation into meal or pelleted feed: 6 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

The product is presented in pack sizes of 500 g, 1 kg and 10 kg packed into polythene bags in polypropylene containers. Not all pack sizes may be marketed.

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

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

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited
Loughrea
Co. Galway
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10987/143/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th March 1996
Date of last renewal: 14th March 2006

10 DATE OF REVISION OF THE TEXT

November 2018