Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Zerofen 22 % Granules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Fenbendazole 222.2 mg/g

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Granules.
White to greyish-white granules.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats

4.2 Indications for use, specifying the target species

Zerofen 22% Granules is indicated for the treatment of immature and mature stages of nematodes of the gastro-intestinal and respiratory tracts of domestic dogs and cats. It also has an ovicidal effect and is indicated for the following:
For the treatment of gastrointestinal nematodes and cestodes of domestic dogs and cats affected with *Ascarid* spp., *Ancylostoma* spp., *Uncinaria* spp., *Trichuris* spp. and *Taenia* spp.. Also for the treatment of lungworm nematodes of domestic dogs affected with *Oslerus (Filaroides) osleri,* and domestic cats affected with *Aelurostrongylus abstrusus*.
For the treatment of pregnant bitches to reduce pre-natal infections with *Toxocara canis* and the transfer of *Toxocara canis* and *Ancylostoma caninum* to their pups *via* the milk.

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

None.

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

Direct contact with the skin should be kept to a minimum. Avoid the inhalation of dust. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Zerofen 22% Granules may be safely used in pregnant and young animals when administered according to the recommended dosing schedules.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

For oral administration only (sprinkled onto food).
For the routine treatment of adult dogs and cats: 100 mg/kg is recommended.
For the treatment of weaned puppies and kittens: 50 mg/kg daily for three days is recommended.
For the control of lungworm, *Oslerus (Filaroides) osleri*, in dogs: 50 mg fenbendazole per kg per day for 7 days. A repeat course of treatment may be required in some cases.
For the control of lungworm, *Aelurostrongylus abstrusus*, in cats: 20 mg fenbendazole/kg per day for five days.
For the treatment of pregnant bitches: daily dosage of 25 mg fenbendazole/kg from day 40 of pregnancy continuously to 2 days post-whelping.
For the treatment of clinical worm infestations in adult dogs and cats: administer 1g Zerofen 22% Granules per 4.4 kg (10 lbs) bodyweight daily for 3 consecutive days (= 50 mg fenbendazole per kg bodyweight daily for 3 days).

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

Not applicable.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Zerofen 22% Granules contain fenbendazole which is a member of the benzimidazole family of anthelmintics and has been in veterinary use for a number of years. Fenbendazole acts against parasites by disrupting the formation of microtubules by binding to tubulin in parasitic intestinal cells thereby preventing the absorption of glucose, such that parasites are gradually starved to death. Fenbendazole displays preference for parasitic as opposed to mammalian tubulin. This appears to be due to the fact that the formation of the parasitic tubulin-fenbendazole complex is more favourable kinetically under physiological conditions than the mammalian complex.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Povidone 30
Sodium Lauryl Sulphate

6.2 Major 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

Store in a dry place.
Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Foil paper sachets composed of 45 or 50 gsm paper/10 gsm polyethylene/8 um foil/25 gsm polyethylene. The product is packed in 1 g, 2 g, 3 g, 4 g and 5 g sachets. Sachets containing 1 g, 2 g and 4 g are available in the following presentations:

100 x 1 g
120 x 1 g
70 x 2 g
120 x 2 g
4 x 4 g.

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

Dispose of used sachet with the household refuse.
Unused product should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited
Loughrea
Co. Galway
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10987/140/001

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