# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zerofen 22% Equine Granules

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

**Active substance**: Fenbendazole 22% w/w

**Excipient(s):**

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

Horses and other equines

### 4.2 Indications for use,specifying the target species

Zerofen 22% Equine Granules is a broad spectrum anthelmintic for the treatment of horses and other equines infected with benzimidazole susceptible immature and mature stages of nematodes of the gastro-intestinal including large redworms (*Strongylus vulgaris, Strongylus edentatus*) and migrating large redworms, benzimidazole susceptible small redworms and encysted mucosal larvae, *Ascarids*, *Oxyuris* and Strongyloides species. Also kills nematode eggs.

### 4.3 Contraindications

Not to be used in animals hypersensitive to the ingredients.

### 4.4 Special warnings

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.

Resistance to Fenbendazole (a benzimidazole) has been reported in cyathostomes in horses in a number of countries, including the EU. 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 to anthelmintics.

## 4.5 Special precautions for use

### Special precautions for use in animals

Veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control and to reduce the likelihood of anthelmintic resistance developing.

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

Direct contact with the skin should be kept to a minimum.

Wash hands after use.

Avoid inhalation of granule dust.

## 4.6 Adverse reactions (frequency and seriousness)

None known.

## 4.7 Use during pregnancy, lactation or lay

Zerofen 22% Equine Granules may be given to pregnant mares and young foals at normal therapeutic dosage levels.

## 4.8 Interaction with other medicinal products and other forms of interaction

None known.

## 4.9 Amounts to be administered and administration route

For oral administration only. Granules should be sprinkled onto concentrate or grain feeds immediately before administration and the full daily dosage given as one administration. Discard any remaining medicated feed.

The dose rate is 7.5 mg fenbendazole/kg bodyweight, equivalent to 10.2 g granules per 300 kg body weight or 2 level measuring scoops.

Assess bodyweight accurately before calculating the dosage. Treatment should be repeated when natural re-infestation with worms occurs (approximately every 6 to 8 weeks).

**Dosage Table:**

| | |
|---|---|
| Foals and ponies up to 300 kg bodyweight | 2 level scoops |
| Thoroughbreds and other breeds of horses up to 600 bodyweight | 4 level scoops |
| Heavy hunters, heavy draught horses | 6 level scoops |
| Donkeys | 1 level scoop |

For the treatment of encysted mucosal stages of Cyathostomes (small strongyles) the dose rate is 30 mg/kg, which is equivalent to 40.5 g granules per 300 kg body weight or 8 level measuring scoops.

For the treatment of migrating stages of *Strongylus vulgaris* and tissue stages of *Strongylus endentatus* the dose rate is 60 mg/kg, which is equivalent to 81 g granules per 300 kg body weight or 16 level measuring scoops.

**OR**

For the control of encysted mucosal stages of small strongyles and migrating larval stages of large strongyles administer 7.5 mg fenbendazole/kg bodyweight daily for 5 days which is equivalent to 10.2 g Zerofen granules per 300 kg bodyweight or 2 level measuring scoops, daily for 5 days. Ideally dosage at this dose rate should be carried out at once a year between the end of October and December. All new arrivals should be treated at this rate whatever the time of year.

For the treatment of diarrhoea caused by *Strongyloides westeri* in 2 to 3 week old suckling foals the dose-rate is 50 mg fenbendazole/kg bodyweight, which is equivalent to 10.2 g Zerofen granules per 44 kg body weight or 2 level measuring scoops.

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

Benzimidazole anthelmintics possess a wide safety margin

### 4.11 Withdrawal period(s)

Animals must not be slaughtered for human consumption until 35 days after treatment.

## 5. PHARMACOLOGICAL PROPERTIES

Anthelminthics (Benzimidazoles and related substances)
ATC code: QP52AC13

### 5.1 Pharmacodynamic properties

Zerofen 22% Equine 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 hence preventing the absorption of glucose, 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 monohydrate
Povidone K30
Sodium lauryl sulphate
Purified Water

### 6.2 Incompatibilities

None known.

### 6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:5 years.

### 6.4. Special precautions for storage

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

### 6.5 Nature and composition of immediate packaging

Foil paper polyethylene sachets containing 10.2 g granules.
High density polyethylene pails with high density polypropylene push-fit lid, containing 1 kg of granules in a low density polythene bag with a 5.1 g styrene measuring scoop.
Not all pack sizes are marketed.

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

Any unused veretinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

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

## 8. MARKETING AUTHORISATION NUMBER(S)

Vm 11990/4017

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31/07/98 / Date of last renewal - 31/07/08

## 10 DATE OF REVISION OF THE TEXT

May 2008