

## Summary of Product Characteristics

### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Orazole 10% w/v Oral Drench

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

#### Active Substance

Fenbendazole 100 mg

#### Excipients

Methyl Parahydroxybenzoate 0.25 mg

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Oral Suspension

A white to off-white suspension.

### 4 CLINICAL PARTICULARS

#### 4.1 Target Species

Cattle

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

For the treatment of immature and mature stages of nematode and cestode infestations of the gastrointestinal and respiratory tracts of cattle, including:

Haemonchus spp., Ostertagia spp., Trichostrongylus spp., Cooperia spp., Nematodirus spp., Bunostomum spp., Trichuris spp., Strongyloides spp., Oesophagostomum spp., Dictyocaulus spp., Moniezia spp.

#### 4.3 Contraindications

The product should not be used in conjunction with bromsalan fasciolicides or against benzimidazole resistant nematodes.

Do not use in animals known to be hypersensitive to the active substance or to any of the excipients.

#### 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

Estimate bodyweight accurately. Use only properly calibrated dosing equipment in good working order. Avoid the introduction of contamination during use.

##### Special precautions to be taken by the person administering the product to Animals

Avoid contact with the product. Wash hands after use.

#### 4.6 Adverse reactions (frequency and seriousness)

None known.

#### 4.7 Use during pregnancy, lactation or lay

The product may be used in pregnant and lactating animals.

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

While there are no known interactions, it is advisable that the product is not mixed with other medicinal products.

#### 4.9 Amounts to be administered and administration route

Shake well before use

Administer Fenbendazole at 7.5 mg/kg bodyweight orally. Practical dose recommendations are as follows

##### Body weight Dose

Up to 65kg	5 ml
66-125kg	10 ml
126-200kg	15 ml
201-270kg	20 ml
271-340kg	25 ml
341-400kg	30 ml

Above 400kg an extra 3.75 ml per 50kg.

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

Not applicable.

#### 4.11 Withdrawal Period(s)

Foodstuffs must not be taken for human consumption during the treatment period.

Cattle:

Edible tissues: 28 days

Milk: 5 days

## **5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Fenbendazole is an established anthelmintic which belongs to the benzimidazole group and is used primarily for its activity against nematodes.

### **5.1 Pharmacodynamic properties**

It blocks fumarate reductase which results in the inhibition of the formation of adenosine triphosphate. There is also evidence that it inhibits glucose uptake and therefore increases glycogen utilisation and depletes the worm's glycogen reserves. The overall effect is to starve the parasite to death.

### **5.2 Pharmacokinetic properties**

Fenbendazole is absorbed poorly and most of the drug is excreted unchanged in the faeces. The metabolites which have been identified are excreted in the urine and bile. Very little is excreted in the milk in cattle. The active and its metabolites are mainly found in the plasma and, over time, in the liver.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Propylene Glycol  
Methyl Parahydroxybenzoate  
Polysorbate 80  
Xanthan Gum  
Simeticone  
Purified Water

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf-life**

Two years

### **6.4 Special precautions for storage**

Store below 25°C. Do not freeze.

### **6.5 Nature and composition of immediate packaging**

1 L, 2 L, 2.5 L and 5 L high density polyethylene containers with tamper evident closures.

Not all pack sizes may be marketed.

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

Empty containers must be rinsed with water before disposal. Dispose of used containers safely. Do not contaminate ponds, waterways or ditches with the product or used containers.

Any unused product or waste material should be disposed of in accordance with national requirements.

**7 MARKETING AUTHORISATION HOLDER**

Foran Healthcare Ltd  
2 Cherry Orchard Industrial Estate  
Dublin 10  
Ireland

**8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10484/12/1

**9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 13<sup>th</sup> August 1991

Date of last renewal: 12<sup>th</sup> August 2006

**10 DATE OF REVISION OF THE TEXT**

January 2016