1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orazole 10% w/v Oral Drench

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:
Fenbendazole 100mg

Excipient:
Methyl Parahydroxybenzoate 0.25mg

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 interactions

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 65 kg	5 ml
66 - 125 kg	10 ml
126 - 200 kg	15 ml
201 - 270 kg	20 ml
271 - 340 kg	25 ml
341 - 400 kg	30 ml
Above 400 kg	an extra 3.75 ml per 50 kg.

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

Not applicable.

4.11 Withdrawal Periods

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 particulars

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

Methyl Parahydroxybenzoate
Propylene Glycol
Polysorbate 80
Xanthan Gum
Simeticone
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-Life

2 years

6.4 Special Precautions for Storage

Store below 25°C.
Do not freeze.

6.5 Nature and composition of immediate packaging

1L, 2L, 2.5L 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 product 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

8 MARKETING AUTHORISATION NUMBER

VPA10484/012/001

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

13/08/1991

10. DATE OF REVISION OF THE TEXT

23/02/2024