1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orazole 100 mg/ml Oral Drench

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance: 100 mg fenbendazole

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl Parahydroxybenzoate (E218)	2.5 mg
Propylene Glycol	
Polysorbate 80	
Xanthan Gum	
Simethicone	
Purified Water	

A white to off-white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each 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.

3.3 Contraindications

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

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 veterinary medicinal product to animals:
Avoid contact with the product. Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used in pregnant and lactating animals.

3.8 Interaction with other medicinal products and other forms of interaction

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

3.9 Administration routes and dosage

Oral use.

Shake well before use.

To ensure a correct dosage, body weight should be determined as accurately as possible.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable

3.12 Withdrawal periods

Meat and offal: 28 days.
Milk: 5 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP52AC13

4.2 Pharmacodynamics

Fenbendazole 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.

4.3 Pharmacokinetics

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 liver.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

Store below 25 °C.
Do not freeze.

5.4 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.

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

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.
Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Foran Healthcare

7. MARKETING AUTHORISATION NUMBER(S)

VPA10484/012/001

8. DATE OF FIRST AUTHORISATION

13th August 1991

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

09 April 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).