1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Curazole 100 mg/ml oral drench for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Fenbendazole 100 mg

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 mg
Propyl parahydroxybenzoate (E216)	0.2 mg
Sodium metabisulphite	1 mg
Polysorbate 80	
Sodium citrate	
Citric acid	
Simethicone emulsion	
Xanthan gum	
Purified water	

A white to off-white oral suspension.

3. CLINICAL INFORMATION

3.1 Target Species

Cattle.

3.2 Indications for use for each target species

The veterinary medicinal product is a broad spectrum anthelmintic for control of immature and mature stages of the following nematodes and cestodes of the gastrointestinal and respiratory tracts of cattle.

Haemonchus spp.
Ostertagia spp.
Trichostrongylus spp.
Cooperia spp.
Nematodirus spp.

Bunostomum spp.
Trichuris spp.
Stongyloides spp.
Oesophagostomum spp.
Dictyocaulus spp.

In cattle it is usually effective against inhibited larvae of Ostertagia and also for control of tapeworms *Moniezia* spp.

3.3 Contraindications

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the 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.

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.
Personal protective equipment consisting of impermeable rubber gloves should be worn when handling the veterinary medicinal product.

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:

This product is safe for use during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.
The recommended therapeutic dose of fenbendazole is 7.5 mg/kg bodyweight.
Shake well before use.
Estimate bodyweight carefully.
Use only properly calibrated dosing equipment.
Practical dosage recommendations:

Bodyweight (kg)	Dose (ml)
To – 65 kg	5 ml
66 – 125 kg	10 ml
126 – 200 kg	15 ml
201 – 270 kg	20ml
271 – 340 kg	25 ml
341 – 400 kg	30 ml
Above 400 kg	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

Cattle:
Meat and offal: 28 days.
Milk: 120 hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AC13

4.2 Pharmacodynamics

Fenbendazole, like many benzimidazoles, blocks fumarate reductase which results in the inhibition of the formation of adenosine triphosphate (involved in mitochondrial energy). There is also evidence that it inhibits glucose uptake and therefore increases glycogen utilization and depletes the worm's glycogen reserve. The overall effect of this action is to effectively starve the parasite to death. Furthermore this action results in the detachment of the parasites but in the case of intestinal helminths this detachment does not result in loss of contact with the drug whereas in the case of the liver fluke such detachment would reduce such contact. This probably explains its limited effect on the liver fluke and the good effect on intestinal helminths.

4.3 Pharmacokinetics

Fenbendazole is poorly soluble in water and consequently is poorly absorbed; something which is reflected in the relatively low plasma levels.
The scheme for the known metabolic pathways is given by Short, Flory, Hsieh and Barker (1988) together with the relative rates of breakdown in various species. The main break down products are the sulphoxide (oxfendazole) and sulphone.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

Do not store above 25°C.
Do not freeze.

5.4 Nature and composition of immediate packaging

1L, (jerrican, flat bottom flexi), 2.5L (jerrican, back pack) and 5L (jerrican) HDPE white rigid containers closed with a polypropylene screw cap with an induction heat seal liner.

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

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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Univet Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10990/015/001

8. DATE OF FIRST AUTHORISATION

07/05/1991

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

11/07/2025

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*).