1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Curazole 50 mg/ml oral drench for cattle and sheep.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Fenbendazole 50.0 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)	2.0 mg
Propyl parahydroxybenzoate (E216)	0.2 mg
Sodium metabisulphite	1.0 mg
Polysorbate 80	
Sodium citrate	
Citric acid	
Simethicone emulsion	
Xanthan gum	
Purified water	

A white to off white suspension.

3. CLINICAL INFORMATION

3.1 Target Species

Cattle and sheep.

3.2 Indications for use for each target species

A broad spectrum anthelmintic for control of benzimidazole susceptible mature and developing immature forms of the following nematodes of the gastrointestinal and respiratory tracts of cattle and sheep.
Cattle: For the treatment of cattle infected with:
Haemonchus spp.
Ostertagia spp.
Trichostrongylus spp.
Cooperia spp.
Nematodirus spp.
Bunostomum spp.
Trichuris spp.

Strongyloides spp.
Oesophagostomum spp.
Dictyocaulus viviparus.

The veterinary medicinal product is usually effective against *Moniezia* spp. of tapeworm and inhibited larvae of *Ostertagia* spp. in cattle.

Sheep: for the treatment of sheep infected with benzimidazole susceptible:
Haemonchus spp.
Ostertagia spp.
Trichostrongylus spp.
Cooperia spp.
Nematodirus spp.
Bunostomum spp.
Chabertia spp.
Strongyloides spp.
Oesophagostomum spp.
Dictyocaulus filaria.

The veterinary medicinal product is usually effective against *Moniezia* spp. of tapeworm and may have useful but variable efficacy against *Trichuris* spp. in sheep.

3.3 Contraindications

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

3.4 Special warnings

When dosing sheep, care must be taken not to damage the mouth or pharyngeal region with drenching equipment. 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:

None.

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

None.

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:

Sheep have been reported to be sensitive to benzimidazoles during the first quarter of gestation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.
Shake well before use.

The recommended therapeutic dose is 7.5 mg of fenbendazole per kg bodyweight (approximately 5 ml per 33 kg bodyweight) for cattle and 5 mg of fenbendazole per kg bodyweight (approximately 1 ml per 10 kg bodyweight) for sheep.

Estimate bodyweight carefully. Use only property calibrated dosing equipment.

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.

Sheep:
Meat and offal: 28 days.
This product should not be used in ewes producing milk for human consumption.

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 reserves. 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

1 L (jerrican, flat bottom flexi), 2.5 L (jerrican, back pack), 5 L (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

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

Univet Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10990/015/003

8. DATE OF FIRST AUTHORISATION

12/03/1992

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

17/02/2026

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*).