Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Curazole 10 %w/v Oral Drench

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance	
Fenbendazole	100 mg

Excipients		
Methyl Parahydroxybenzoate (E218)	2	mg
Propyl Parahydroxybenzoate (E216)	0.2	mg
Sodium Metabisulphite	1	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

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*.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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 minimun.
Wash hands after use.
Wear suitable protective clothing including impermeable rubber gloves.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

This product is safe for use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

The recommended therapeutic dose of fenbendazole is 7.5 mg/kg bodyweight.
For oral administration in cattle.
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.

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

Not applicable.

4.11 Withdrawal Period(s)

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 28 days from the last treatment.
Milk for human consumption must not be taken during treatment. Milk for human consumption may be taken from cows only after 120 hours from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Fenbendazole is an anthelmintic belonging to the benzimidazole group which acts by blocking fumerate reductase which results in the inhibition of the formulation of adenosine triphosphate (involved in mitochondrial energy).

5.1 Pharmacodynamic properties

Fenbenazole, 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.

5.2 Pharmacokinetic properties

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
Sodium metabisulphite
Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)
Sodium Citrate
Citric Acid
Simethicone Emulsion
Xanthan Gum
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not store above 25^0C.
Do not freeze.

6.5 Nature and composition of immediate packaging

1 L (jerrican, flat bottom flexi), 2.5 L (jerrican, back pack) and 5 L (jerrican) HDPE white containers closed with a HDPP screw cap with a wood pulp PVDC liner.

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 product or used containers.
Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Univet Ltd.
Tullyvin
Cootehill
Cavan

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10990/015/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

7th May 2006

10 DATE OF REVISION OF THE TEXT

September 2012