Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT
Curazole 5 %w/v Oral Drench.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance
Fenbendazole 50.0 mg/ml

Excipients
Methyl Parahydroxybenzoate (E218) 2.0 mg/ml
Propyl Parahydroxybenzoate (E216) 0.2 mg/ml
Sodium Metabisulphite 1.0 mg/ml
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 and Sheep.

4.2 Indications for use, specifying the 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.

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

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

4.4 Special warnings for each target species
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.

4.5 Special precautions for use

Special precautions for use in animals
None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
None.

4.6 Adverse reactions (frequency and seriousness)
None known.

4.7 Use during pregnancy, lactation or lay
Sheep have been reported to be sensitive to benzimidazoles during the first quarter of gestation.

4.8 Interaction with other medicinal products and other forms of interaction
None known.

4.9 Amounts to be administered and administration route
For oral administration in cattle and sheep. 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
Not applicable.

4.11Withdrawal Period(s)
Animals must not be slaughtered for human consumption during treatment. Cattle and sheep 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.
This product should not be used in ewes producing milk for human consumption.

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 formation of adenosine triphosphate (involved in mitochondrial energy).

5.1 Pharmacodynamic properties
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.

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 25oC.
Do not freeze.

6.5 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.

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 10990/015/003

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
11th March 2007

10 DATE OF REVISION OF THE TEXT
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