1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Curazole 100 mg/ml oral suspension for horses.

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 suspension.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

For the treatment of immature and mature stages of nematodes of the gastro-intestinal and respiratory tract, including encysted mucosal small strongyle larvae (cyathostomes). The veterinary medicinal product has an ovicidal effect on roundworm eggs.
For the treatment of horses infected with adult large strongyles and adult and larval small strongyles.
For the treatment of ascarids and *Oxyuris equi*.

3.3 Contraindications

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

3.4 Special warnings

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each individual animal / herd.

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a herd, maintenance of susceptible refugia is essential to reduce that risk. Systematically applied interval-based treatment and treatment of a whole herd should be avoided. Instead, if feasible, only selected individual animals or subgroups should be treated (targeted selective treatment). This should be combined with appropriate husbandry and pasture management measures. Guidance for each specific herd should be sought from the responsible veterinarian.

Resistance to benzimidazoles has been reported in gastro-intestinal nematodes in horses.
The use of this product should take into account local information about susceptibility of the target parasites, where available. It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (e.g. the Faecal Egg Count Reduction Test). Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

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

People with known hypersensitivity to fenbendazole or any of the listed excipients should avoid contact with the veterinary medicinal product.
Do not eat, drink or smoke while handling the product.
Direct contact with the skin should be kept to a minimum. Wear suitable protective clothing including impermeable rubber gloves. Wash hands after use.
If accidental contact with the skin or eyes occurs, wash off any skin contamination with soap and water immediately. Rinse the affected eyes thoroughly with clean, fresh water. Remove any contaminated clothing immediately.

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 also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

For oral administration.
The suspension should be shaken well before use and is ready for use without further dilution.
To ensure a correct dosage, body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended; accuracy of the dosing device should be checked.

Routine dosage for horses:
7.5 mg fenbendazole/kg bodyweight as a single dose corresponding to 7.5 ml per 100 kg bodyweight.
Examples:

Body weight	Volume
Up to 100 kg	7.5 ml
100-200 kg	15 ml
200-300 kg	22.5 ml
300-400 kg	30 ml

For bodyweight in excess of 400 kg use 30 ml plus an additional 3.75 ml per 50 kg.
Treatment of specific indications in horses:
For the treatment of mucosal stages of *Trichonema* spp. - 30 mg/kg.
For the treatment of migrating stages of *Strongylus vulgaris* and *Strongylus edentatus* - 60 mg/kg.
Alternatively for the treatment of migrating larval stages of large strongyles and encysted mucosal stages of small strongyles (cyathostomes) administer 7.5 mg/kg fenbendazole daily for five days.
Diarrhoea caused by *Strongyloides westeri* in sucking foals should be treated with a dose of 25 ml of the veterinary medicinal product per 50 kg bodyweight (50 mg fenbendazole/kg bodyweight).

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

None known.

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: 31 days
Not authorised for animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP52AC13

4.2 Pharmacodynamics

Fenbendazole is an anthelmintic belonging to the benzimidazole-carbamate group. It acts by interfering with the energy metabolism of the nematode. The anthelmintic affects both adult and immature stages of gastro-intestinal and respiratory nematodes. This anthelmintic efficacy is based on inhibition of the polymerisation of tubulin to microtubuli.

4.3 Pharmacokinetics

Fenbendazole is only partly absorbed after oral administration and is then metabolised in the liver. The half-life of fenbendazole in serum after oral application of the recommended dose of 7.5 mg/kg bodyweight is 7.6 hours in horses with a C_{max} of 153 ng/ml.
Fenbendazole and its metabolites are distributed throughout the body but highest concentrations are found in the liver. The elimination of fenbendazole and its metabolites occurs primarily via the faeces (>90%) and to a smaller extent as well in the urine and milk. Fenbendazole is metabolised to its sulfoxide, then to sulfone and amines.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

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) and 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 product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as fenbendazole may be dangerous for fish and other aquatic organisms.

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 10990/015/004

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: DD month YYYY.

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

MM/YYYY

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.