Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Curafluke 10% w/v Oral Drench

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances
Fenbendazole 100 mg
Rafoxanide 100 mg

Excipients
Propyl parahydroxybenzoate (E216) 0.1 mg
Methyl parahydroxybenzoate (E218) 1 mg
Quinoline yellow (E104) 0.09 mg
Sodium metabisulphite (E223) 0.5 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.
A pale lemon suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

The product permits a three way activity against Fluke, Lungworms and Stomach Worms in Cattle. It is a broad spectrum anthelmintic for the treatment of benzimidazole susceptible mature and immature stages of nematodes and cestodes of the gastrointestinal and respiratory tracts of cattle. Rafoxanide is active against immature and mature *Fasciola* sp.

CATTLE:
Haemonshus sp.
Ostertagia sp.
Trichostrongylus sp.
Cooperia sp.
Nematodirus sp.
Bunostomum sp.
Trichuris sp.
Strongyloides sp.
Oesophagostomum sp.
Dictyocaulus sp.
Moniezia sp.
Fasciola sp. (mature and immature over 8 weeks of age)

The product has a good therapeutic effect against type II *Ostertagiasis*

4.3 Contraindications

Not for use against Benzimidazole resistant nematodes.

Do not use in cases of hypersensitivity to the active substances.

4.4 Special warnings for each target species

Where a dosing gun is used to administer the product, care should be taken to avoid causing injury to the mouth and pharynx of animals. Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing which may be due to underestimation of bodyweight, misadministration of the product, or lack of calibration of the dosing device.

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the tests strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

4.5 Special precautions for use

Special precautions for use in animals
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

Fenbendazole and rafoxanide are safe for use during pregnancy.
See section 4.11

4.8 Interaction with other medicinal products and other forms of interactions

None known

4.9 Amounts to be administered and administration route

The recommended therapeutic dose of fenbendazole and rafoxanide is 11.25 mg/kg bodyweight of each active for cattle.
For oral administration in cattle.
To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked. If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.
Shake well before use.
Practical dosage recommendations are as follows:
Cattle: 11.25 ml per 100 kg bodyweight

Bodyweight (kg)	**Dose (ml)**
CATTLE	
50	5.60
100	11.25
300	33.75
500	56.25

The veterinary surgeon should give advice regarding appropriate dosing programmes and stock management to achieve adequate parasite control.

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

The product is well tolerated in cattle at three times the recommended dosage

4.11 Withdrawal period(s)

Animals must not be slaughtered for human consumption during treatment or for 60 days thereafter

Milk: Not authorised for use in animals producing milk for human consumption including during the dry period. Do not use during the last trimester of pregnancy in heifers which are intended to produce milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics; combinations of benzimidazoles and related substances ATCvet code: QP52AC30

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.
Rafoxanide (QP52AG05) is a salicylanilide anthelmintic and these are known to be potent uncouplers of oxidative phosphorylation in animal tissues. *In vitro* experiments indicate that salicylanilides, including the commercially used flukicides, oxyclozanide and rafoxanide, uncouple oxidative phosphorylation in *Fasciolahepatica* and other parasites.

5.2 Pharmacokinetic particulars

Fenbendazole
Fenbendazole is absorbed poorly from the gastro-intestinal tract leading to with low plasma levels of fenbendazole, oxfendazole and sulphone. It is mainly excreted in the faeces though some of the metabolites that have been identified are excreted in the urine and bile. The active and its metabolites are mainly found in the plasma.

Rafoxanide
Kinetic studies of rafoxanide in cattle have shown that it is absorbed into the blood with a mean peak concentration of *circa* 23 $\mu g.ml^{-1}$ achieved in 2 to 3 days. Plasma are considerably higher than those in tissues. Only one metabolite has been identified (3, 5-di-iodosalicylic acid) and this was found in blood tissues and milk. There is little known or reported on the excretion of rafoxanide though apparently it is excreted in the bile.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Xanthan Gum
Quinoline Yellow (E104)
Simethicone Emulsion
Propyl Parahydroxybenzoate (E216)
Methyl Parahydroxybenzoate (E218)
Polysorbate 80
Sodium Citrate
Sodium Metabisulphite (E223)
Citric Acid Monohydrate
Purified Water

6.2 Major incompatibilities

None known

6.3 Shelf-life

Shelf life of the veterinary medicinal product packaged in white LDPE containers: 3 years.

6.4 Special precautions for storage

Do not store above 25°C
Protect from light.
Protect from frost.

6.5 Nature and composition of immediate packaging

1 L (jerrican, back pack), 2.5 L (jerrican, back pack) or 5 L (jerrican, backpack) HDPE white containers closed with a HDPP screw cap with a wood pulp PVDC liner. The product may be marketed with or without an outer carton.
Not all pack sizes may be marketed

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements

7 MARKETING AUTHORISATION HOLDER

Univet Limited
Tullyvin
Cootehill
Co. Cavan.
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10990/032/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15 September 2000
Date of last renewal: 06 August 2010

10 DATE OF REVISION OF THE TEXT

December 2017