Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Curafluke 5% w/v Oral Drench

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of suspension contains:

Active Substance		
Fenbendazole	50.00	mg
Rafoxanide	50.00	mg
Excipients		
Propyl parahydroxybenzoate	0.10	mg
Methyl parahydroxybenzoate	1.00	mg
Quinoline yellow (E104)	0.09	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 and sheep.

4.2 Indications for use, specifying the target species

Curafluke 5% Oral Drench permits a three way activity against Fluke, Lungworms and Stomach Worms in Cattle and Sheep. 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 and sheep.

Rafoxanide is active against immature and mature *Fasciola hepatica* (mature and immature over 8 weeks of age).

4.2 Indications for use, specifying the target species (Cont/d)

Cattle and Sheep:
Haemonchus sp.
Ostertagia sp.
Trichostrongylus sp.
Cooperia sp.
Nematodirus sp.
Bunostomum sp.
Trichuris sp.
Strongyloides sp.
Oesophagostomum sp.
Dictyocaulus sp.
Moniezia sp.
Fasciola hepatica (mature and immature over 8 weeks of age).
The product has a good therapeutic effect against type II *Ostertagiasis*.

4.3 Contraindications

None.

4.4 Special warnings for each target species

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 under-estimation of the bodyweight, mis-administration of the product or lack of calibration of the dosing device (if any).

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 on anthelmintics resistance developing. If the product does not achieve the desired clinical effect, other diseases, nutritional diseases or anthelmintic resistance may be involved.

4.5 Special precautions for use

Special precautions for use in animals
Where a dosing gun is used to administer the product care must be taken to avoid the occurrence of dosing gun pharyngitis.

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

For oral administration in cattle and sheep.

For sheep, the recommended therapeutic dose is 7.5 mg fenbendazole and 7.5 mg rafoxanide per kilogram bodyweight. For cattle, the recommended therapeutic dose is 11.25 mg fenbendazole and 11.25 mg rafoxanide per kilogram bodyweight.

Shake well before use
Estimate bodyweight carefully.
Use only properly calibrated dosing equipment.
Practical dosage recommendations are as follows:

Bodyweight (Kg)	**Dose (ml)**
CATTLE	
50	11.25
100	22.5
400	90.0
> 400 kg	11.25 ml/50 kg
SHEEP	
10	1.5

50	7.5

At 2 months after housing, when dosing cattle for worms and adult fluke, a lower dose of 7.5 mg/kg can be used i.e. 7.5 ml per 50kg bodyweight, 30 ml per 200 kg or 75 ml per 500 kg.

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

Curafluke 5% Oral Drench is well tolerated in cattle at three times the recommended dosage

4.11 Withdrawal period(s)

Meat:
Cattle - 60 days. Animals intended for human consumption may be slaughtered only from 60 days after the last treatment.
Sheep - 54 days. Animals intended for human consumption may be slaughtered only from 54 days after the last treatment.

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. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QP52AC30
Pharmacotherapeutic Group: Anthelmintics, combinations of benzimadazoles and related substances.

Curafluke 5% Oral Drench is a broad spectrum anthelmintic.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Xanthan gum (E415)
Quinoline yellow (E104)
Simethicone emulsion
Propyl parahydroxybenzoate (E216)
Methyl parahydroxybenzoate (E218)
Polysorbate 80
Sodium citrate (E331)
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 as packaged for sale:
White HDPE containers: Three years

6.4 Special precautions for storage

Store below 25°C.
Protect from light and frost.

6.5 Nature and composition of immediate packaging

1L (jerrican, backpack), 2.5L (jerrican, backpack) or 5L (jerrican, backpack) HDPE white containers with a HDPP screw cap and 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

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 Limited
Tullyvin
Cootehill
Co. Cavan.
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10990/032/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 05 September 1997
Date of last renewal: 04 September 2007

10 DATE OF REVISION OF THE TEXT

January 2018