Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Fenben 10 Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:	
Active substance	
Fenbendazole	100 mg
Excipients	
Potassium Sorbate	1.8 mg
Formaldehyde Solution	2.0 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Mature Cattle and Calves.

4.2 Indications for use, specifying the target species

Effective against benzimidazole sensitive mature and immature roundworms, including Type II Ostertagia, lungworms and tapeworms in cattle.

4.3 Contraindications

Do not use in animals with known hypersensitivity to active ingredient. Do not use in cattle producing milk for human consumption.

4.4 Special warnings for each target species

Cattle with heavy lungworm infection may suffer an allergic response to the treatment as a result of killing worms in situ.

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

As with all oral drenches, care must be taken to avoid injury to the mouth and pharynx when using standard drenching equipment.

Special Precautions to be taken by the Person Administering the Medicinal Product to Animals

Any contact with skin or eyes should be washed away immediately with water.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Fenbendazole is not embryotoxic.
Can be used during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use at the same time as Bromsalans.

4.9 Amounts to be administered and administration route

The product is administered orally. The recommended dosage rate is 7.5 ml of the product per 100 kg bodyweight equivalent to 7.5 mg Fenbendazole/kg bodyweight.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible. 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.
Use properly calibrated dosing equipment.

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

Fenbendazole is extremely safe with a safety factor in excess of 100 times the recommended dose.

4.11 Withdrawal Period(s)

Animals intended for human consumption must not be slaughtered during treatment. Cattle intended for human consumption may only be slaughtered from 21 days after the last treatment.
Not for use in animals producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, benzimadazoles and related substances
ATCvet code: QP52AC13

5.2 Pharmacokinetic properties

Fenbendazole is slowly absorbed from the gut and peak blood levels are attained 28-30 h post treatment. Amongst the many metabolites are the corresponding sulphone and sulphoxide, the latter is identical to Oxfendazole and may be responsible for its activity. Up to 35% of the dose is eliminated in the urine, most is excreted in the faeces.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium Sorbate
Formaldehyde Solution
Colloidal Anhydrous Silica
Xanthan Gum
Propylene Glycol
Polyoxyl 40 Stearate
Polyethylene Glycol
Citric Acid
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packed for sale: 2 years.

6.4 Special precautions for storage

Do not store above 25^{o}C.
Protect from light.
Protect from frost.
Store in a dry place in the original container. Keep the container tightly closed.

6.5 Nature and composition of immediate packaging

White HDPE packs with polypropylene screw caps. Packs contain 1 litre (flat bottom backpack), 2.5 litre (jerrican) and 5 litre (jerrican).

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Ancare (Ireland) Limited,
30 Coolmine Business Park,
Clonsilla Road,
Dublin 15.

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10915/002/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th February 1994
Date of last renewal: 9th February 2009

10 DATE OF REVISION OF THE TEXT

June 2013