Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Ranide 30 mg/ml Oral Drench

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains :

Active substance:
Rafoxanide 30 mg

Excipients include :
Sodium Metabisulphite (E223) 0.5 mg
Quinoline Yellow (E104) 0.09 mg
Propyl Parahydroxybenzoate (E216) 0.1 mg
Methyl Parahydroxybenzoate (E218) 1 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral Suspension.
A yellow aqueous suspension

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and sheep.

4.2 Indications for use, specifying the target species

For the treatment of fascioliasis in cattle and sheep and also nasal worm, *Oestrus ovis*, in sheep. *Ranide Oral Drench* is active against *Fasciola Hepatica* (mature and immature fluke over 8 weeks of age).

4.3 Contraindications

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

4.4 Special warnings for each target species

Irreversible liver damage may have occurred before treatment is given. This can lead to death in severe cases irrespective of treatment.
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
Where a dosing gun is used to administer the product, care must be taken to avoid causing injury to the mouth or pharynx.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash splashes from eyes and hands immediately.
Wash hands after use

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

See section 4.11

4.8 Interaction with other medicinal products and other forms of interaction

Ranide Oral Drench should not be diluted or mixed with other products before administration.

4.9 Amounts to be administered and administration route

For oral use in cattle and sheep only.
Shake well before use.
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.
To be given orally at a dose rate of 7.5 mg Rafoxanide/kg bodyweight for sheep and 11.25 mg Rafoxanide/kg for cattle.
Practical dosage recommendations are as follows:

Cattle	**Sheep**
50 kg - 18.75 ml	10 kg - 2.5 ml
100 kg - 37.5 ml	15 kg - 3.5 ml
150 kg - 56.25 ml	20 kg - 5.0 ml
200 kg - 75.0 ml	25 kg - 6.5 ml
250 kg - 93.75 ml	30 kg - 7.5 ml

The dose for heavier animals is an additional 18.75 ml per 50 kg for cattle and 2.5 ml per 10 kg for sheep.
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

Ranide Oral Drench tolerance studies have shown that the product is well tolerated in cattle and sheep at three times the recommended dosage. No significant changes were observed in haematological measurements or blood biochemical parameters over a 28-day period post treatment.

4.11Withdrawal Period(s)

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

Pharmacotherapeutic group: Anthelmintics
ATCvet code: QP52AG05

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

Store below 25°C.
Do not freeze.

6.5 Nature and composition of immediate packaging

1L (jerrican), 2.5L (jerrican and backpack) or 5L (jerrican and flexipack), 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

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
Co. Cavan
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10990/027/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15th February 2010

10 DATE OF REVISION OF THE TEXT