Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Rafazole Oral Suspension.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:		
Active Substances		
Rafoxanide	30	mg
Levamisole Hydrochloride	30	mg
Excipients		
Sodium Metabisulphite (E223)	1	mg
Tartrazine (E102)	0.075	mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, Sheep.

4.2 Indications for use, specifying the target species

Rafazole is effective in the treatment and control of roundworm, lungworm and fluke infections in cattle and sheep. It is highly effective against mature and developing immature stages of levamisole-susceptible major stomach and bowel worm species including *Trichostrongylus* spp, *Cooperia* spp, *Ostertagia* spp (except *Ostertagia* larvae in cattle), *Haemonchus* spp, *Nematodirus* spp, *Bunostomum* spp, *Oesophagostomum* spp, *Chabertia* spp and lungworms (*Dictyocaulus* spp.). Rafazole is effective against mature liverfluke in cattle and sheep.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredients.
Do not use in animals less than 6 months of age.

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 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

Where a dosing gun is used to administer the product, care should be taken to avoid the occurrence of dosing gun pharyngitis.
Shake the container before use.
Avoid the introduction of contamination during use.
Not to be diluted or mix with other products.

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

When using do not eat, drink or smoke.
Wash hands and exposed skin before meals and after work.
Remove immediately any contaminated clothing.
Wash splashes from eyes and skin immediately.
Levamisole can cause idiosyncratic reactions and serious blood disorders in a very small number of people. If symptoms such as dizziness, nausea, vomiting or abdominal discomfort are experienced when using the product, or sore mouth/throat or fever occur shortly afterwards, then medical advice should be sought immediately.

4.6 Adverse reactions (frequency and seriousness)

Occasionally, at the recommended dose, cattle may show signs of lip-licking and slight muscle tremors.

4.7 Use during pregnancy, lactation or lay

Rafazole is safe for use during pregnancy (see section 4.11).

4.8 Interaction with other medicinal products and other forms of interaction

Animals should not be treated simultaneously with products containing organophosphorous compounds or diethyl carbamazine citrate.
Any such treatment should not take place within 14 days before or after the use of Rafazole.

4.9 Amounts to be administered and administration route

For oral administration only using properly calibrated dosing equipment. Estimate bodyweight accurately. 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.

One ml of Rafazole contains 30 mg of Rafoxanide and 30 mg of Levamisole HCl.

The dose rate for cattle and sheep is 7.5 mg levamisole HCl and 7.5 mg rafoxanide per kg bodyweight, equivalent to 12.5 ml of Rafazole per 50 kg bodyweight.

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

Clinical signs of toxicity include lip-licking, increased salivation, muscle tremors and head-shaking.

4.11 Withdrawal Period(s)

Animals intended for human consumption must not be slaughtered during treatment. Cattle and sheep may be slaughtered for human consumption only after 60 days from the last treatment.
Cattle: Not authorised for use in cattle producing milk for human consumption, including pregnant cattle intended to produce milk for human consumption.
Sheep: Not authorised for use in ewes producing milk for human consumption including during the dry period. 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, levamisole combinations.

ATCvet code: QP52AE51

5.1 Pharmacodynamic properties

Rafazole contains both rafoxanide, a fasciolicide, and levamisole HCl and anthelmintic in fixed combination. Rafoxanide is a salicylanide derivative and has been used as a fasciolicide for several years. It acts by uncoupling oxidative phosphorylation in the parasitic cells, gradually depriving them of energy. Because it is highly protein bound it is only activated when released from the plasma proteins by the action of blood sucking organisms and therefore is selective for fasciola and blood sucking organisms. It is absorbed slowly, binds to plasma proteins and is slowly eliminated from the body.

Levamisole is the l-isomer of the anthelmintic tetramisole. It acts as a cholinergic agonist causing depolarising ganglionic blockade of the parasite’s neuromuscular junction. It is quickly and extensively absorbed form the gastrointestinal tract and is also quickly eliminated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium Hydrogen Phosphate Dodecahydrate
Citric Acid Monohydrate
Disodium Edetate
Sodium Metabisulphite (E223)
Colloidal Anhydrous Silica
Xanthan Gum
Polysorbate 20
Propylene Glycol
Silica in Dimeticone Suspension
Tartrazine (E102)

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

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

1, 2.5, 5 and 10 litre.
High density polyethylene containers with polyethylene closures.
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

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10987/012/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT

January 2014