Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

WORMALL 2.265%w/v Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Oxfendazole 2.265 % w/v

Excipients:
Sodium Methyl Parahydroxybenzoate 0.18 %w/v

3 PHARMACEUTICAL FORM

Oral suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and Sheep

4.2 Indications for use, specifying the target species

WORMALL is a broad spectrum anthelmintic for the treatment and control of mature and developing immature gastro-intestinal roundworms and lungworms and also tapeworms in cattle and sheep. WORMALL is ovicidal for strongyle eggs.

For the treatment of cattle and sheep infested with benzimidazole susceptible strains of the following species:

Gastro-Intestinal Roundworms:
Ostertagia
Haemonchus
Trichostrongylus
*Nematodirus (*including *N. battus)*
Cooperia
Capillaris
Oesophagostomum
Chabertia
Trichuris

Lungworms:
Dictyocaulus

Tapeworms:
Monezia

In cattle, it is also effective against inhibited larvae of *Cooperia spp.* and usually effective against inhibited/arrested larvae of *Ostertagia spp*.. In sheep, it is effective against inhibited/arrested larvae of *Nematodirus spp*., and benzimidazole susceptible *Haemonchus spp.* and *Ostertagia spp*..

4.3 Contraindications

WORMALL is contra-indicated in animals with known hypersensitivity to the active ingredient.
Do not use in sheep producing milk for human consumption.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

As with any husbandry procedure, care should be taken when handling the animals especially when inserting the dosing gun nozzle into the animal's mouth.
Unnecessary force should not be used as this may cause damage to the mouth and pharyngeal region.
Shake well before use.

Equipment should be thoroughly cleaned before and after dosing.
Do not exceed the stated dose.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Avoid contact with the skin and eyes. Wash any splashes immediately with cold water.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

WORMALL is safe for use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

For oral administration only.

Shake well before use.

Cattle: 4.5mg oxfendazole per kg bodyweight.

bodyweight	**dose**
100kg (2 cwt)	20ml
150kg (3 cwt)	30ml
200kg (4 cwt)	40ml
250kg (5 cwt)	50ml
300kg (6 cwt)	60ml

Above 300kg give 10ml per 50kg

Sheep: 5.0 mg oxfendazole per kg bodyweight.

bodyweight	**dose**
Up to 14kg (30lb)	2.5ml
15-27kg (31-60lb)	5.0ml
28-40kg (61-90lb)	7.5ml
41-54kg (91-120lb)	10.0ml
55-67kg (121-150lb)	12.5ml
Over 67kg (150lb)	15.0ml

Give the recommended dose by mouth using standard dosing equipment. After treatment, animals should be moved to clean pasture in order to prevent re-infection. Where this is not done, regular re-treatment may be necessary.

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

Not applicable.

4.11 Withdrawal Period(s)

Cattle should not be slaughtered for human consumption until 14 days after treatment.
Sheep should not be slaughtered for human consumption until 10 days after treatment.
Milk for human consumption must not be taken during treatment.
Milk for human consumption may only be taken from a cow after 5 days from the last treatment.
Not to be used in sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antihelmintics, oxfendazole.

ATCvet Code: QP52AC02

5.1 Pharmacodynamic properties

Oxfendazole, (methyl [5-phenylsulphinyl-1-H-benzimidazole-2-yl] carbamate), belongs to a class of compounds, the benzimidazoles.

The Benzimidazoles possess anti-mitotic properties, and this action is related to their capacity to bind to tubulin leading to inhibition of formation of microtubules. This, in turn, leads to disruption of cell division. Eventually cell lysis and disintegration occur. Oxfendazole may concentrate preferentially in intestinal cells of parasites to exert its toxic effects initially and principally at this site. Similar effects do not occur in host cells, possibly because of differential binding characteristics. The disruption of parasite metabolic processes, and the effects of oxfendazole on enzymes of helminth parasites, involves inhibition of glucose and sodium uptake, reduced muscle glycogen content, uncoupling of oxidative phosphorylation and inhibition of malate dehydrogenase and fumarate reductase.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Mehyl Parahydroxybenzoate Trisodium Citrate
Citric Acid
Sodium Metabisulphite Di Sodium Edetate
Polysorbate 80 Xanthan Gum
Simethicone Emulsion Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

The shelf-life expiry date of WORMALL should not exceed 4 years from the date of manufacture.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

WORMALL will be presented in 500 ml, 1.0 L, 2.5 L, 5 L and 10 L multi-dose polyethylene containers with polyethylene closures.

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 guidelines for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Coyle Veterinary Products Limited
Unit 5
Kilkerrin Park
Liosbaun Industrial Estate
Tuam Road
Galway

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10889/002/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th May 1994

Date of last renewal: 30th May 2004

10 DATE OF REVISION OF THE TEXT

November 2015