Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxfencare Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance		
Oxfendazole	22.65	mg

Excipients		
Formaldehyde Solution	2.0	mg
Potassium sorbate	1.0	mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.
Aqueous off white free flowing suspension

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and sheep.

4.2 Indications for use, specifying the target species

For the control of sensitive mature and immature gastrointestinal roundworms, lungworms and tapeworms in cattle and sheep, including:

Gastro-intestinal roundworms:
Ostertagia spp.
Haemonchus spp.
Trichostrongylus spp.
Nematodirus spp., including *N. battus*
Cooperia spp.
Capillaria spp.
Oesophagostomum spp.
Chabertia spp.
Trichuris spp.

Lungworms:
Dictyocaulus spp.

Tapeworms:*Monezia* spp.

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active ingredient.Do not use in sheep producing milk for human consumption.

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 body weight, 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 test(s) 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

Do not exceed stated dose.
When treating sheep great care must be taken to avoid trauma to the pharyngeal area with the nozzle of drenching guns.

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

Direct contact with the skin should be kept to a minimum.
Wear suitable protective clothing including impermeable rubber gloves.Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Oxfendazole is not embryotoxic.This product can be used during pregnancy.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

Shake well before use.
Using standard drenching equipment administer orally.
To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.
The recommended dose rates are: Cattle, 4.5 mg Oxfendazole/kg
Sheep, 5.0 mg Oxfendazole/kg
Example:

CATTLE		**SHEEP**	
Liveweight	*Dose*	*Liveweight*	*Dose*
100 kg (2 cwt)	20 ml	Up to 15 kg	3 ml
150 kg (3 cwt)	30 ml	16 - 20 kg	4 ml
200 kg (4 cwt)	40 ml	21 - 25 kg	5 ml
250 kg (5 cwt)	50 ml	26 - 30 kg	6 ml
300 kg (6 cwt)	60 ml	31 - 35 kg	7 ml
350 kg (7 cwt)	70 ml	36 - 40 kg	8 ml
400 kg (8 cwt)	80 ml	41 - 45 kg	9 ml
Over 400 kg	Give 10 ml/50 kg	Over 45 kg	Give 1 ml/5 kg

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

This product is very well tolerated, at the recommended dose rates. In the case of accidental overdosage, depression and anorexia may occur.

4.11 Withdrawal period(s)

Animals intended for human consumption must not be slaughtered during treatment. Cattle and sheep intended for human consumption may only be slaughtered from 28 days after the last treatment. Milk intended for human consumption may only be taken from cows after 4 days from the last treatment.Do not use in sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, benzimidazoles and related substances
ATCvet code: QP52AC02

5.1 Pharmacodynamic properties

Oxfendazole is an anthelmintic belonging to the benzimidazole (I – BZ) class of compounds.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Anhydrous Citric Acid
Formaldehyde Solution
Propylene Glycol
Polyethylene Glycol 6000
Polyoxyl 40 Stearate
Potassium Sorbate
Colloidal Anhydrous Silica
Xanthan Gum Water Purified

6.2 Major incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not store above 25°C.
Store in a dry place in the original container and 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 (flat bottom backpack), 5 litre (jerrican) and 10 litre (jerrican).
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

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

7 MARKETING AUTHORISATION HOLDER

Ancare Ireland Ltd.
30 Coolmine Business Park,
Clonsilla Road,
Dublin 15.
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10915/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

8th June 2007

10 DATE OF REVISION OF THE TEXT

January 2022