SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovex 2.265% w/v Oral Suspension for Cattle and Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:	**mg**
Oxfendazole	22.65

Excipients:	
Methyl Parahydroxybenzoate	2.0
Propyl Parahydroxybenzoate.	0.2

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral Suspension
White to off-white coloured suspension

4. CLINICAL PARTICULARS

4.1 Target species

Cattle and sheep

4.2 Indications for use, specifying the target species

A broad spectrum worm drench for cattle and sheep indicated for the control of mature and developing immature forms of gastrointestinal roundworms, lungworms and tapeworms. The product is also ovicidal against nematode eggs.

In **cattle** it is active against the following species:
Roundworms: *Ostertagia* spp*, Haemonchus* spp*, Trichostrongylus* spp*, Nematodirus, Cooperia* spp*, Capillaria* spp*, Oesophagostomum* spp*, Chabertia* spp*,* and *Trichuris* spp*;*
Lungworms: *Dictyocaulus* spp*;*
Tapeworms: *Moniezia* spp.
It is usually effective in the control of Type II Ostertagiasis.

In **sheep** it is active against benzimidazole susceptible strains of the following species:
Roundworms: *Ostertagia* spp*, Haemonchus* spp*, Trichostrongylus* spp*, Nematodirus,* (including *N. battus), Cooperia* spp*, Oesophagostomum* spp*,* and *Chabertia* spp (also provides useful control of *Trichuris).*
Lungworms: *Dictyocaulus* spp*;*

Tapeworms: *Moniezia* spp

4.3 Contraindications

Not for use in animals known to be hypersensitive to the active ingredient.

4.4 Special warnings for

Care must be taken not to damage the pharyngeal region when dosing, particularly in sheep.
Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with a veterinary surgeon.

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 (if any).

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.
Resistance to benzimidazoles (which include oxfendazole) has been reported in Teladorsagia, Haemonchus, Cooperia and Trichostrongylus species in small ruminants in a number of countries, including the EU. Resistance to albendazole has been reported in Cooperia and Teladorsagia species in cattle in developed countries such as New Zealand. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selsction for resistance to anthelmintics.

4.5 Special precautions for use

i. Special precautions for use in animals

Assess bodyweight as accurately as possible before calculating the dosage.

ii. Special precautions for the person administering the veterinary medicinal product to animals

Avoid contact with the skin and eyes. Wash any splashes immediately with cold water. 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

No known contra-indications for the use of Bovex 2.265% during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Shake the container before use. Avoid the introduction of contamination during use. For oral administration only using properly calibrated dosing equipment. Estimate bodyweight accurately. Each ml of Bovex 2.265% contains 22.65 mg oxfendazole.

The dosage rates are as follows:

Cattle: 4.5 mg oxfendazole per kg bodyweight, equivalent to 5 ml per 25 kg bodyweight.
Sheep: 5 mg oxfendazole per kg bodyweight, equivalent to 1 ml per 4.5 kg bodyweight.

Dosage Guide:

Cattle		**Sheep**	
Bodyweight	**Dose**	**Bodyweight**	**Dose**
100 kg (2 cwt)	20 ml	Up to 9 kg (19 lb)	2.0 ml
150 kg (3 cwt)	30 ml	10 to 13.5 kg (22 to 30 lb)	3.0 ml
200 kg (4 cwt)	40 ml	14 to 18 kg (31 to 40 lb)	4.0 ml
250 kg (5 cwt)	50 ml	19 to 22.5 kg (42 to 49.5 lb)	5.0 ml
300 kg (6 cwt)	60 ml	23 to 27 kg (51 to 59 lb)	6.0 ml

Cattle above 300 kg should be given a further 5 ml for each additional 25 kg bodyweight.
Sheep above 27 kg should be given a further 1 ml for each additional 4.5 kg bodyweight.

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.
Do not mix with other products.

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

No treatment specified. Benzimidazoles has a wide margin of safety.

4.11 Withdrawal period

Cattle:
Meat: 19 Days
Milk: 84 hours
Sheep:
Meat: 24 Days

Not for use in sheep producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics: Benzimidazoles and related substances; Oxfendazole

ATCvet code: QP52AC02

5.1 Pharmacodynamic properties

The active ingredient is oxfendazole, one of the benzimidazole group of compounds with anthelmintic activity. Benzimidazoles bind to nematode tubulin, a protein necessary for the formation and viability of microtubules, primarily in the absorptive intestinal cells of the nematode. This results in a complete absence of microtubules in the intestinal cells leading to a reduction in the absorption of nutrients, a reduction in glycogen and the effective starvation of the parasite.
Structural differences between tubulin from mammalian and helminth sources results in the preferential toxicity of oxfendazole to the helminth and not to the host. Benzimidazoles have also been shown to inhibit the fumarate reductase system of helminths and impair energy production.

5.2 Pharmacokinetic properties

Oxfendazole is slowly and incompletely absorbed after oral administration, with C_{max} reached between 15 and 30 hours, followed by slow elimination. This slow rate of absorption and elimination means that the drug is in contact with the helminths for significantly long periods of time. Oxfendazole has four main metabolites fenbendazole, fenbendazole sulphone, *p*-hydroxy fenbendazole and fenbendazole amine. While oxfendazole and fenbendazole are anthelmintically active, the other metabolites have minimal or no anthelmintic activity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate
Propyl parahydroxybenzoate
Citric Acid monohydrate
Sodium Citrate
Colloidal anhydrous Silica
Xanthan Gum

Povidone 90
Polysorbate 20
Propylene Glycol
Simethicone emulsion
Water Purified

6.2 Incompatibilities

Not to mix the product with other medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4 Special precautions for storage

Protect from frost. Protect from direct sunlight.

6.5 Nature and composition of immediate packaging

1 litre, 2.5 litre, 5 litre and 10 litre white high-density polyethylene jerricans with polyethylene (screw-fit) closures.

1 litre, 2.5 litre and 5 litre high-density polyethylene flexipacks with polypropylene (screw-fit) closures.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused product or waste material should be disposed of in accordance with national requirements. Do not contaminate ponds, waterways or ditches with the product or used container.

7. MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
H62 FH90
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 08749/5179

9. DATE OF FIRST AUTHORISATION

21 March 1994

10. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

September 2025

Gavin Hall
Approved: 11 November 2025