Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovex 2.265%

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance		
Oxfendazole	2.265	%w/v
Excipients		
Methyl Parahydroxybenzoate (E218)	0.2	%w/v
Propyl Parahydroxybenzoate (E216)	0.02	%w/v

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.
A cream coloured suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, Sheep

4.2 Indications for use, specifying the target species

Bovex 2.265% is a broad spectrum worm drench for cattle and sheep indicated for the treatment and control of mature and immature gastrointestinal roundworms, lungworms and tapeworms. It is also ovicidal. Bovex 2.265% is active against:-
Roundworms: *Ostertagia* spp, *Haemonchus* spp, *Trichostrongylus* spp, *Nematodirus*, (including *N. battus*), *Cooperia* spp, *Capillaria* spp, *Oesophagostomum* spp, *Chabertia* spp, and *Trichuris* spp.
Lungworms: *Dictyocaulus* spp,
Tapeworms: *Moniezia* spp.

It is also effective in the prevention and control of Type II Ostertagiasis.

4.3 Contraindications

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

4.4 Special warnings for each target species

Care must be taken not to damage the pharyngeal region when dosing, particularly in sheep.

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.

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.

4.5 Special precautions for use

Special precautions for use in animals

Avoid the introduction of contamination during use.

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

Wash splashes of the product from skin immediately.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Bovex 2.265% can be safely used 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

For oral administration only using properly calibrated dosing equipment. Estimate bodyweight accurately. One ml of Bovex 2.265% contains 22.65 mg oxfendazole.

Cattle: 4.5 mg oxfendazole per kg bodyweight.

Sheep: 5 mg oxfendazole per 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. 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.

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

Not applicable.

4.11 Withdrawal Period(s)

Animals intended for human consumption should not be slaughtered during treatment. Cattle must not be slaughtered for human consumption until 14 days after the last treatment. Sheep must not be slaughtered for human consumption until 21 days after the last treatment. Milk intended for human consumption may only be taken from cows 84 hours after the last treatment.

Do not administer to sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharacotherapeutic Group: Anthelmintics; Benzimidazoles and related substances; Oxfendazole

ATCvet Code: QP52AC02

5.1 Pharmacodynamic properties

Bovex 2.265% is a broad spectrum worm drench for cattle and sheep indicated for the treatment and control of mature and immature gastrointestinal roundworms, lungworms and tapeworms. It is also ovicidal. Benzimidazoles bind to nematode tubulin, a protein necessary for the formation and viability of microtubules. This occurs primarily in absorptive intestinal cells resulting in a complete absence of microtubules in the intestinal cells of the nematode, which means that these cells cannot absorb nutrients, a consequent reduction in glycogen and effective starvation of the parasites. Structural differences have been shown to exist between tubulin from mammalian and helminth sources, thus resulting 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 peak plasma levels reached between 15 and 30 hours followed by slow elimination of the drug. This slow rate of absorption and elimination means that the drug is in contact with the helminths for significantly long periods of time, a key factor in the efficacy against gastrointestinal nematodes.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)
Citric Acid Monohydrate
Sodium Citrate
Colloidal Anhydrous Silica
Xanthan Gum
Povidone 90
Polysorbate 20
Propylene Glycol
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

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

1 litre, 2.5 litre, 5 litre and 10 litre high density polyethylene containers and 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.
Do not contaminate ponds, waterways or ditches with product or used containers.

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10987/039/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

5th August 2002

10 DATE OF REVISION OF THE TEXT

May 2013