1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovex 22.65 mg/ml Oral suspension for Cattle and Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Oxfendazole 22.65 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate (E218)	2 mg
Propyl parahydroxpbenzoate (E216)	0.2 mg
Citric Acid monohydrate	-
Sodium Citrate	-
Colloidal anhydrous Silica	-
Xanthan Gum	-
Povidone 90	-
Polysorbate 20	-
Propylene Glycol	-
Simethicone emulsion	-
Purified water	-

A cream coloured suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and sheep.

3.2 Indications for use for each target species

The veterinary medicinal product 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.
The veterinary medicinal product 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.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each individual animal.

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a herd/flock, maintenance of susceptible refugia is essential to reduce that risk. Systematically applied interval-based treatment and treatment of a whole herd/flock should be avoided. Instead, if feasible, only selected individual animals or subgroups should be treated (targeted selective treatment). This should be combined with appropriate husbandry and pasture management measures. Guidance for each specific herd/flock should be sought from the responsible veterinarian.

Resistance to benzimidazoles (which includes oxfendazole) has been reported in *Teladorsagia*, *Haemonchus*, *Cooperia* and *Trichostongylus* species in small ruminants in a number of countries, including the EU. 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 selection for resistance to anthelmintics.

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.
- Under dosing, which may be due to underestimation of bodyweight, 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Avoid the introduction of contamination during use.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash splashes of the product from skin immediately.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the label for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The veterinary medicinal product can be safely used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

For oral administration only using properly calibrated dosing equipment. Estimate bodyweight accurately. One ml of the veterinary medicinal product contains 22.65 mg oxfendazole.

Cattle: 4.5 mg oxfendazole per kg bodyweight.

Sheep: 5 mg oxfendazole per kg bodyweight.

To ensure a correct dosage, 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable

3.12 Withdrawal Periods

Cattle:
Meat and offal: 14 days.
Milk: 84 hours.

Sheep:
Meat and offal: 21 days.

Not authorised for use in sheep producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP52AC02.

4.2 Pharmacodynamics

The veterinary medicinal product 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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 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.

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

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

Do not contaminate ponds, waterways or ditches with product or used containers.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10987/039/001

8. DATE OF FIRST AUTHORISATION

05/08/1992

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

19/07/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).