

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One ml of Bovex 2.265% contains 22.65 mg oxfendazole.

3. PHARMACEUTICAL FORM

Oral Suspension

4. PACKAGE SIZE

5 L
10 L

5. TARGET SPECIES

Cattle and Sheep

6. INDICATION(S)

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

In **cattle** it is active against the following species:

Roundworms: *Ostertagia*, *Haemonchus*, *Trichostrongylus*, *Nematodirus*, *Cooperia*, *Capillaria*, *Oesophagostomum*, *Chabertia* and *Trichuris*.

Lungworms: *Dictyocaulus*

Tapeworms: *Moniezia*

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*, *Haemonchus*, *Nematodirus* (including *N. batfus*), *Trichostrongylus*, *Cooperia*, *Oesophagostomum* and *Chabertia* (also provides useful control of *Trichuris*)

Lungworms: *Dictyocaulus*

Tapeworms: *Moniezia*

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 selection for resistance to anthelmintics.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration only using properly calibrated dosing equipment. Shake container before use.

Cattle: 4.5mg oxfendazole per kg bodyweight i.e. 5 ml per 25 kg bodyweight.

Sheep: 5 mg oxfendazole per kg bodyweight i.e. 1 ml per 4.5 kg bodyweight.

Cattle			Sheep		
Bodyweight	Dose	No. of Doses per 5/10 L pack	Bodyweight	Dose	No. of Doses per 5/10 L pack
100 kg (2 cwt)	20 ml	250 / 500	Up to 9 kg (19 lb)	2.0 ml	2,500 / 5,000
150 kg (3 cwt)	30 ml	166 / 333	10 to 13.5 kg (22 to 30 lb)	3.0 ml	1,666 / 3,333
200 kg (4 cwt)	40 ml	125 / 250	14 to 18kg (31 to 40 lb)	4.0 ml	1,250 / 2,500
250 kg (5 cwt)	50 ml	100 / 200	19 to 22.5 kg (42 to 49.5 lb)	5.0 ml	1,000 / 2,000
300 kg (6 cwt)	60 ml	83 / 166	23 to 27 kg (51 to 59 lb)	6.0 ml	833 / 1,666
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, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

8. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 19 days from the last treatment. Sheep may be slaughtered for human consumption only after 24 days from the last treatment. Milk for human consumption must not be taken during treatment. Milk for human consumption may be taken from cows only after 84 hours from the last treatment. Do not use in sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Care must be taken not to damage the pharyngeal region, particularly in sheep, when dosing. Assess bodyweight as accurately as possible before calculating the dosage. Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with your Veterinary Surgeon.

Operator warnings: 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. Do not mix with other products.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Protect from frost. Protect from direct sunlight.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority. Do not contaminate ponds, waterways or ditches with the product or used container.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]

For animal treatment only

POM-VPS

To be supplied only on veterinary prescription UK authorised veterinary medicinal product

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Animal Health Ltd.,
7 Rodney Street
Liverpool
L1 9HZ
England

16. MARKETING AUTHORISATION NUMBER(S)

Vm 11990/4008

17. MANUFACTURER'S BATCH NUMBER

Approved: 03/05/2018

A handwritten signature in black ink, appearing to read 'J. Long', is written below the approval date.