MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Chanelle Animal Health Ltd., 7 Rodney St., Liverpool L1 9HZ, UK.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zerofen Worm Drench 2.5% w/v Oral Suspension for Sheep and Cattle

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Fenbendazole 10% w/v

4. PHARMACEUTICAL FORM

Oral suspension

5. PACKAGE SIZE

1, 2.5 and 10 litre

6. INDICATION(S)

Zerofen 2.5% is a broad spectrum anthelmintic for the control of mature and developing immature forms of the major species of roundworms in sheep and cattle.

In sheep it is effective against benzimidazole susceptible strains of the following parasites: Gastro-intestinal roundworms: *Ostertagia, Haemonchus*, *Trichostrongylus*, *Nematodirus*, *Cooperia*, *Oesophagostomum*, *Chabertia*, *Bunostomum* and *Strongyloides* species. Lungworms: *Dictyocaulus filaria*.

In cattle it is effective against the following parasites: Gastro-intestinal roundworms: *Ostertagia*, *Cooperia*, *Trichostrongylus*, *Nematodirus*, *Haemonchus*, *Oesophagostomum*, *Bunostomum Strongyloides* and *Trichuris* species. Lungworms: *Dictyocaulus viviparus.*

It is usually effective for the control of tapeworms, *Moniezia* spp, in sheep. The product may be useful for the control of *Trichuris* in sheep. It is usually effective against inhibited larvae of *Ostertagia* species in cattle. Zerofen has an ovicidal effect on nematode eggs.

7. CONTRAINDICATIONS

8. ADVERSE REACTIONS

9. TARGET SPECIES

Cattle and sheep

10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Sheep: Give as an oral drench at the rate of 5 mg fenbendazole per kg bodyweight (approximately 1 ml per 5 kg bodyweight).

Cattle: Give as an oral drench at the rate of 7.5 mg fenbendazole per kg bodyweight (approximately 3ml per 10kg bodyweight).

CATTLE	
Bodyweight	**Dose**
50 kg	15 ml
100 kg	30 ml
150 kg	45 ml
200 kg	60 ml
250 kg	75 ml
300 kg	90 ml
350 kg	105 ml
Over 350 kg give 15 ml per 50 kg.	

SHEEP	
Bodyweight	**Dose**
Up to 15 kg	3 ml
16 - 25 kg	5 ml
26 - 35 kg	7 ml
36 - 50 kg	10 ml
51 - 65 kg	13 ml
66 - 75 kg	15 ml
Over 75 kg give 2 ml per 10 kg.	

To ensure administration of the correct dose, bodyweight should be determined as accurately as possible. Accuracy of the dosing device must be checked.

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment. Sheep may be slaughtered for human consumption only after 21 days from the last treatment. Cattle may be slaughtered for human consumption only after 14 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 132 hours from the last treatment. The product must not be used in sheep producing milk for human consumption.

13. SPECIAL STORAGE PRECAUTIONS

Do not freeze. Shake container before use.

14. SPECIAL WARNING(S)

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

Do not mix with other products.

Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk dosing programmes should be discussed with your veterinary adviser. 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 the 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 has been reported in *Teladorsagia Haemonchus*, *Cooperia* and *Trichostrongylus* species in small ruminants. 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.

15. EXPIRY DATE

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

DANGEROUS to aquatic life. Do not contaminate ponds, waterways or ditches with product or used containers. Dispose of any unused product or containers in accordance with guidance from your local waste regulation authority.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

18. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

[Distribution category]

POM-VPS

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children

20. MARKETING AUTHORISATION NUMBER(S)

Vm 11990/4000

21. MANUFACTURER’S BATCH NUMBER

22. OTHER INFORMATION

1-BZ Fenbendazole belongs to the Benzimidazole (1-BZ) class of anthelmintics.

Approved: 04/01/2018