PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

CONTAINER LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Triclacert 5% Oral Suspension for Sheep
Oral Suspension for Sheep
Triclabendazole, 5% w/v

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active Ingredient: Triclabendazole, 5% w/v
Other Ingredients: Each ml contains 2.0mg Methyl Parahydroxybenzoate (E218) and 0.2mg Propyl Parahydroxybenzoate (E216) as preservatives, and brilliant blue (E133).

3. PHARMACEUTICAL FORM

Fluke Drench.
Oral Suspension.

4. PACKAGE SIZE

(0.8L), (1L), (2.2L), (2.5L), (5L)

This product is available in pack sizes of 0.8L, 1L, 2.2L, 2.5L and 5L. Not all pack sizes may be marketed.

5. TARGET SPECIES

Sheep

6. INDICATION(S)

For the treatment of fasciolosis in sheep, caused by early immature, immature and adult stages of liver fluke (*Fasciola hepatica*) susceptible to triclabendazole.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake container well before use. Use unaltered product from the original container.

For oral administration only using properly calibrated dosing equipment. To ensure administration of a correct dose, bodyweight should be determined as accurately as possible. 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 over- dosing.

The recommended dose rate is 10 mg Triclabendazole per kg bodyweight as a single administration, which is equivalent to 2.0 ml Triclaben 5% per 10 kg bodyweight. Triclaben 5% can be used in pregnant sheep.

DOSAGE GUIDE:

Bodyweight	Dosage	Bodyweight	Dosage
Up to 10 kg	2 ml	40 kg	8 ml
15 kg	3 ml	50 kg	10 ml
20 kg	4 ml	60 kg	12 ml
25 kg	5 ml	70kg	14 ml
30 kg	6 ml	80kg	16 ml

For animals over 80 kg - give an additional 2 ml for each additional 10 kg bodyweight.

DOSING PROGRAMME:
The timing for treatment should be based on epidemiological factors and should be customized for each individual farm. A dosing programme should be established by the veterinary surgeon.

Anthelmintics are agents that destroy or result in the expulsion of susceptible parasitic worms. Parasite resistance to a particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class. To reduce this risk, dosing programmes should be discussed with a veterinary surgeon.
Triclaben contains the anthelmintic Triclabendazole. Fluke (*Fasciola hepatica*) resistance to triclabendazole has been identified, and losses associated with resistant strains of fluke in sheep flocks treated with triclabendazole can be significant. If signs of fascioliasis continue after treatment with Triclaben, DO NOT REPEAT THE DOSE and do not dose with other products containing triclabendazole. Seek veterinary advice. If resistance is suspected or confirmed, you should change active ingredient on veterinary advice.

8. WITHDRAWAL PERIOD

Meat and offal: 56 days.
Milk: Not authorised for use in ewes producing milk for human consumption including during the dry period. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Contraindications
Do not use in cases of known hypersensitivity to the active ingredient

Adverse effects
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

Special warnings
Only use for liverfluke strains susceptible to triclabendazole.
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 under estimation 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 triclabendazole has been reported in liver fluke (*F hepatica*) in sheep. Therefore, the use of this product should be based on local (regional farm) epidemiological information about susceptibility of the liver fluke and recommendations on how to limit further selection for resistance to anthelmintics.

Care must be taken not to damage the mouth or pharyngeal region when dosing. Clean drenching equipment before and after use.

The administration of the product is well tolerated in target species when given on a single occasion at 3 times the recommended dose. Following the administration of triclabendazole at 100 mg/kg or more (10x the recommended dose), reduced appetite, increased blood urea nitrogen and shifts in serum alpha-2-globulin were observed, with a slight increase in absolute liver weight.

Operator Warnings
When using the product do not eat, drink or smoke. Wear gloves. Wash splashes from eyes and skin immediately. Take off any contaminated clothing immediately. Wash hands and exposed skin before meals and after work. In cases of hypersensitivity and contact allergy, direct skin contact and inhalation should be avoided.

Environmental Warnings
Triclaben 5% may have toxic effects on fish and aquatic invertebrates. Sheep must not have any access to surface water such as streams, ponds or ditches within 7 days after treatment with Triclaben. When spreading manure from treated animals on arable lands a safety distance of 10 m to adjacent surface waters must be kept.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Protect from frost.

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

Triclaben 5% may have toxic effects on fish and aquatic invertebrates. Do not contaminate ponds, waterways or ditches with the product or empty container. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

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

Marketing Authorisation Holder: Chanelle Animal Health Ltd., 7 Rodney Street, Liverpool L1 9HZ, UK.

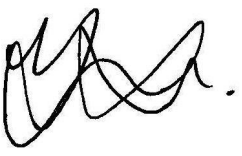
Manufacturer for the batch release: Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 11990/4051

17. MANUFACTURER'S BATCH NUMBER

Batch No.:



Approved: 10 August 2020