PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

CONTAINER LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tribex 5% 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), (2.2L), (5L)

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

5. TARGET SPECIES

Sheep

6. INDICATION(S)

For the treatment of acute, sub-acute and chronic 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

For oral administration only using properly calibrated dosing equipment. Estimate bodyweight as accurately as possible before calculating the dosage. The recommended dose rate is 10 mg Triclabendazole per kg bodyweight as a single administration, which is equivalent to 2.0 ml Tribex 5% per 10 kg bodyweight. Tribex 5% can be safely given to 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:

Routine treatment (Areas of heavy fluke infection)

As a guide, dose all sheep exposed to fluke infected pastures preventatively at regular intervals of 10 weeks from March/April through to October/November. In situations where stock are out-wintered another dose in January may be required. All animals grazing the pasture should be treated at these times. All bought in animals should be dosed before joining the main flock. Veterinary advice should be sought with regard to specific preventative dosing regimes.

Routine treatment (Areas of moderate fluke infection)

Dose all sheep on fluke infected pastures at intervals of 10 weeks throughout the fluke season, usually September to January/ February. All bought in animals should be dosed before joining the main flock.
An additional preventative treatment in the Spring will assist in reducing the amount of new infestation on pasture in the following Autumn.

Treatment of acute outbreaks

The flock should be treated immediately after diagnosis and veterinary advice should be sought for subsequent dosing intervals. If a preventative fluke dosing programme is employed the occurrence of acute fluke is greatly reduced. Re-treatment may not be carried out within 8 weeks.

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

Special warnings for each target species
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 *Fasciola hepatica* in sheep. Therefore, the use of this product should be based on local (regional / farm) epidemiological information about susceptibility of the *Fasciola hepatica* and recommendations on how to limit further selection for resistance to anthelmintics.

Special precautions for use in animals
Only use for liverfluke strains susceptible to triclabendazole. Care must be taken not to damage the mouth or pharyngeal region when dosing. Clean drenching equipment before and after use. Shake container before use. Use unaltered product from the original container.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
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.

Other precautions
The use of Tribex 5% may have harmful 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 Tribex. 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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach 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 Limited, 7 Rodney Street, Liverpool L1 9HZ, United Kingdom.

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

16. MARKETING AUTHORISATION NUMBER

Vm 11990/4033

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

Approved: 26 July 2018

D Austin