

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

CONTAINER LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Triclacert 10% Oral Suspension for Cattle
Oral Suspension for Cattle
Triclabendazole, 10% w/v

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active Ingredient: Triclabendazole, 10% w/v.
Other Ingredients: Each ml contains 2.0mg Methyl Parahydroxybenzoate (E218) and 0.2mg Propyl Parahydroxybenzoate as preservatives, and carmoisine supra (E122).

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

Cattle

6. INDICATION(S)

For the treatment of fasciolosis in cattle, 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; 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 over-dosing.

The recommended dose rate is 12 mg Triclabendazole per kg bodyweight as a single administration, which is equivalent to 6.0 ml Triclaben 10% per 50 kg bodyweight. Triclaben 10% can be used in pregnant cattle.

DOSAGE GUIDE:

Bodyweight	Dosage	Bodyweight	Dosage
50 kg	6 ml	250 kg	30 ml
100 kg	12 ml	300 kg	36 ml
150 kg	18 ml	350 kg	42 ml
200 kg	24 ml	400 kg	48 ml

For animals over 400 kg - give an additional 6 ml for each additional 50 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.

A lasting result, however, can only be expected by involving all potential hosts (domestic ruminants, horse, game animals) in an extensive control programme. The same treatment days should be used for cattle and sheep when a liver fluke dosing programme is implemented and they are grazing the same pasture concurrently; an appropriate authorised product should be used in sheep. All bought animals, suspected to be infected with liver flukes, should be dosed before joining the main herd.

8. WITHDRAWAL PERIOD

Meat and offal: 56 days.

Milk: The product is not permitted for use during lactation in animals producing milk for human consumption. When used in non-lactating cattle: Milk for human consumption may only be taken from 84 hours after calving. Not intended for use within 41 days of calving. If calving occurs before 41 days after treatment, milk for human consumption may only be taken after 41 days plus 84 hours after the treatment.

9. SPECIAL WARNING(S), IF NECESSARY

Contraindications

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

Adverse effects

Occasionally, inflammation of the unpigmented skin, including the udder and the teats, may occur after treatment in cattle exposed to intense sunshine.

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 (*Fasciola hepatica*) in cattle. Therefore, the use of this product should be based on local 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. A single oral overdose of 150 – 200 mg triclabendazole/kg of live bodyweight may lead to side effects such as unsteady gait, dullness and reduced appetite. These side effects are slight and last 1 to 5 days. An antidote is not known.

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 10% may have toxic effects on fish and aquatic invertebrates. Cattle 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 10% 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

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co Galway
H62 FH90
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08749/5083

17. MANUFACTURER’S BATCH NUMBER

Batch No.: