ENDOFLUKE ORAL SUSPENSION

DATA SHEET

100mg/ml Triclabendazole



INDICATIONS

For the treatment of adult, immature and early immature stages of liver fluke susceptible to triclabendazole in cattle and sheep.

LIST No	UNIT PACKAGE	CASE SIZE
1END022	1L	12
1END031	2.5L	6
1END034	5L	4

See reverse for Administration & Dosage

* Milk for human consumption should only be taken from after 48 hours after calving. Not intended for use within 45 days of calving. See 'withdrawals' section overleaf for further information.

BENEFITS

- Triclabendazole-based fluke treatment
- Kills early immature, immature, and adult liver fluke
- Complete chronic and acute fluke control in both cattle and sheep
- Low volume dose helps ensure accurate dosing of stock
- Approved for dairy cattle* use





ENDOFLUKE

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PRESENTATION

A white to off-white suspension for oral administration only. Each ml contains 100mg of triclabendazole.

TARGET SPECIES

Cattle & Sheep.

USES

For the treatment of adult, immature and early immature stages of liver fluke (Fasciola hepatica) susceptible to triclabendazole.

CONTRAINDICATIONS

Do not use in animals known to be hypersensitive to the active substance.

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 underestimation of body weight, misadministration of the product or lack of calibration of the dosing device.

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 cattle and 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

i) Special precautions for use in animals

Care should be taken when dosing animals to avoid causing injury to the mouth and pharynx.

ii) Special precautions to be taken by the person administering the product to animals

When using, do not eat, drink or smoke.

Wash splashes from eyes and skin immediately.

Take off immediately any contaminated clothing.

Wash hands and exposed skin before meals and after use. **iii) Other precautions**

The use of this product may have harmful effects on fish and aquatic invertebrates.

Cattle and sheep must not have any access to the surface water such as streams, ponds or ditches within 7 days after treatment. When spreading manure from treated animals on arable lands, a safety distance of 10m to adjacent surface waters must be kept.

ADVERSE REACTIONS (FREQUENCY AND SERIOUSNESS)

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

Use during pregnancy, lactation or lay

The product is safe for use during pregnancy and lactation. However, concerning use during lactation in dairy cows refer to Withdrawal section.

Interaction with other medicinal products and other forms of interaction

None known.

Amounts to be administered and administration route

For single oral administration only using properly calibrated dosing equipment.

The product is suitable for most types of automatic drenching guns.

Shake the container before use. Use unaltered from original container. Clean drenching equipment before and after use.

DOSAGE

Endofluke 100 mg/ml is given as an oral drench and is suitable for most types of automatic drenching guns.

The recommended dose rate is 12mg triclabendazole per kg body weight in cattle and 10mg triclabendazole per kg body weight in sheep.

CATTLE

6 ml per 50kg bodyweight		
Animal Weight	Dose of product	
50kg	6ml	
100kg	12ml	
150kg	18ml	
200kg	24ml	
250kg	30ml	
300kg	36ml	
350kg	42ml	
400kg	48ml	
For each additional 50kg	6ml	

SHEEP

1 ml per 10kg bodyweight		
Animal Weight	Dose of product	
10kg	1ml	
20kg	2ml	
30kg	3ml	
40kg	4ml	
50kg	5ml	
60kg	6ml	
For each additional 10kg	1ml	

To ensure administration of a correct dose, body weight 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 underor overdosing.

The timing for re-treatment should be based on epidemiological risk patterns and should be customised for each individual farm.

To avoid the potential for the accumulation of residues following repeat administration of the product; animals should not be treated with a frequency of less than 10 weeks

OVERDOSE

A single oral dose of 150-200 mg triclabendazole/kg of live body weight 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.

WITHDRAWAL PERIODS

MEAT & OFFAL: **Cattle:** 56 days **Sheep:** 56 days MILK:

Cattle: Milk for human consumption may only be taken from 48 hours after calving.

Not intended for use within 45 days of calving. Should a cow calve earlier than 45 days after the last treatment, milk for human consumption may only be taken from 45 days + 48 hours (47 days) after the last treatment.

Sheep: 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

SHELF LIFE

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

SPECIAL PRECAUTIONS FOR STORAGE

Protect from frost.

NATURE AND CONTENTS OF IMMEDIATE PACKAGING

1 litre, 2.5 litre and 5 litre high-density polyethylene flat bottom backpack containers containing a white to off-white smooth suspension. The closures used for both pack sizes are 38 mm propylene standard caps with an induction heat seal liner.

A 38 mm polypropylene spouted cap is also provided with each pack size for dispensing purposes.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL

PRODUCT OR WASTE MATERIAL DERIVED FROM THE USE OF SUCH PRODUCTS

The product may have toxic effects on fish and aquatic invertebrates. Any unused product or waste material must not enter surface water and should be disposed of in accordance with national requirements.

LEGAL CATEGORY

LM

MARKETING AUTHORISATION NUMBER

VPA 22033/060/001

MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited 2, 3 & 4 Airton Close, Airton Road Tallaght, Dublin 24, Ireland Tel: +353 (0) 1 466 7900

A full product SPC is available on request from Bimeda or alternatively can be found on the HPRA website.

TAKE TIME



www.bimeda.ie

