ENDOFLUKE

100 mg/ml Oral Suspension

Triclabendazole 100mg/ml

DATA SHEET

INDICATIONS

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

BENEFITS

- Licensed for use in dairy cows
- Chronic and acute fluke control in cattle and sheep
- Tried and trusted triclabendazole-based fluke treatment
- Kills early-immature, mature and adult liver fluke

LIST No	UNIT PACKAGE	CASE SIZE
1END023	2.5L	6
1END034	5L	6

See reverse for Administration & Dosage

ENDOFLUKE

100 mg/ml Oral Suspension

Triclabendazole 100mg/ml

PRESENTATION
A white to off-white suspension for oral administration containing 100mg/ml triclabendazole

TARGET SPECIES
Cattle and sheep

INDICATIONS FOR USE
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 bodyweight, 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 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 IN ANIMALS
Care should be taken when dosing animals to avoid causing injury to the mouth and pharynx.

SPECIAL PRECAUTIONS TO BE TAKEN BY THE PERSON ADMINISTERING THE PRODUCT
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.

OTHER PRECAUTIONS
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
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 AND LACTATION
The product is safe for use during pregnancy and lactation. However, the product is not permitted for use during lactation in animals producing milk for human consumption (see withdrawal periods).

INTERACTIONS/ INCOMPATIBILITIES
None known

AMOUNTS TO BE ADMINISTERED AND ADMINISTRATION ROUTE
For single oral administration only using properly calibrated dosing equipment. Clean drenching equipment before and after use. Shake the container before use.

Endofluke 100 mg/ml is given as an oral drench and is suitable for most types of automatic drenching guns. Use unaltered from original container.
The recommended dose rate is 12mg triclabendazole per kg bodyweight in cattle and 10mg triclabendazole per kg bodyweight in sheep.

PRACTICAL DOSAGE GUIDE:

SHEEP		
1 ml per 10kg bodyweight		
Animal Weight	**Dose of product**	**Dose of product**
10kg	1ml	2500
20kg	2ml	1250
30kg	3ml	833
40kg	4ml	625
50kg	5ml	500
60kg	6ml	416
For each additional 10kg allow 1ml		

CATTLE		
6 ml per 50kg bodyweight		
Animal Weight	**Dose of product**	**Dose per 2.5L Pack**
50kg	6ml	416
100kg	12ml	208
150kg	18ml	138
200kg	24ml	104
250kg	30ml	83
300kg	36ml	69
350kg	42ml	59
400kg	48ml	52
For each additional 50kg allow 6ml		

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 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 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.

WITHDRAWAL PERIODS
Cattle (meat and offal): 56 days
Cattle (milk): 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 (meat & offal): 56 days
Sheep (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.

PHARMACODYNAMIC PROPERTIES
Triclabendazole is a narrow spectrum anthelmintic. The drug accumulates significantly in both immature and adult stages of *Fasciola hepatica* and stimulates the major routes of the parasite's energy generating system, as demonstrated by glucose derived acetate and propionate formation. Triclabendazole inhibits colchicine binding to microtubular proteins suggesting interference of the drug with microtubular structure and function. The drug strongly inhibits the release of proteolytic enzymes in immature and adult parasites, a process dependant on microtubular functions. The precise molecular mode of action of this fasciolicidal drug remains to be elucidated.

PHARMACOKINETIC PARTICULARS
50-75% is absorbed from the gastrointestinal tract and rapidly is almost completely oxidised to its sulfoxide and sulfone. In cattle triclabendazole sulfoxide reaches peak concentrations approximately 27 hours after administration and the sulfone reaches peak concentrations 64 to 72 hours after administration. In sheep triclabendazole sulfoxide reaches peak concentrations approximately 20 hours after administration and the sulfone reaches peak concentrations 30 to 32 hours after administration. Both metabolites bind strongly to plasma proteins, particularly albumin. Metabolites are excreted via the bile mainly as conjugates. More than 90%- 95% of the total dose of triclabendazole is excreted in the faeces, about 2% in the urine and less than 1% in the milk. Elimination is virtually complete by 10 days after administration.

EXCIPIENTS
Xanthan Gum, Methyl Parahydroxybenzoate, Propyl Parahydroxybenzoate, Citric Acid Anhydrous, Sodium Citrate, Polysorbate 80, Silica Colloidal, Anhydrous Simethicone Emulsion, Water, purified

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

STORAGE
Protect from frost.

DISPOSAL
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
POM-VPS

MARKETING AUTHORISATION NUMBER
Vm 50146/4018

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TAKE TIME  OBSERVE LABEL DIRECTIONS

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