SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Endofluke 100 mg/ml Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Triclabendazole 100 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Xanthan Gum	
Methyl Parahydroxybenzoate (E218)	2 mg
Propyl Parahydroxybenzoate (E216)	0.2 mg
Citric Acid Anhydrous	
Sodium Citrate	
Polysorbate 80	
Silica Colloidal	
Anydrous Simethicone Emulsion	
Water, purified	

A white to off-white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and sheep.

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

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 veterinary medicinal 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 veterinary medicinal 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 veterinary medicinal 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.

Special precautions for the protection of the environment:
The use of this veterinary medicinal 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 10 metres to adjacent surface waters must be kept.

3.6 Adverse events

Cattle:

Undetermined frequency (cannot be estimated from the available data)	Skin inflammation[1]

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

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation. However, the veterinary medicinal product is not permitted for use during lactation in animals producing milk for human consumption.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.
For single oral administration only.
The use of suitably calibrated dosing equipment is recommended.
The veterinary medicinal 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:
Cattle: The recommended dose rate is 12 mg triclabendazole per kg bodyweight.
Sheep: The recommended dose rate is 10 mg triclabendazole per kg bodyweight.

Practical Dosage Guide:
Cattle: 6 ml per 50 kg bodyweight

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

Sheep: 1 ml per 10 kg bodyweight

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

Underdosing could result in ineffective use and may favour resistance development.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Accuracy of the dosing device should be thoroughly 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.

For infestations with *Fasciola hepatica*, the need for and frequency of re-treatment(s) should be based on professional advice and should take into account the local epidemiological situation and the animal's lifecycle.

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Cattle:
Meat and offal: 56 days
Milk: Not authorised for use in lactating animals producing milk for human consumption.
When used during the dry period in dairy cows, 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 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AC01

4.2 Pharmacodynamics

Triclabendazole differs from other benzimidazoles in that it 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. However, under these conditions the parasite's motility decreased, indicating that the drug is not associated with inhibition of the energy generating pathways. 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.

4.3 Pharmacokinetics

50 – 75% of the orally administered dose of triclabendazole is absorbed from the gastrointestinal tract. Very rapidly, absorbed triclabendazole is almost completely oxidised to its sulfoxide and sulfone. In cattle triclabendazole sulfoxide reaches peak concentrations approximately 27 hours after administration of the veterinary medicinal product and the sulfone reaches peak concentrations 64 to 72 hours after

administration. In sheep triclabendazole sulfoxide reaches peak concentrations approximately 20 hours after administration of the veterinary medicinal product 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. The elimination is virtually complete by 10 days after administration.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

Protect from frost.

5.4 Nature and composition of immediate packaging

High-density polyethylene flat bottom backpack sealed with 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.

Pack size:
1L
2.5L
5L
Carton box containing 1 backpack containing 1L of product.
Carton box containing 1 backpack containing 2.5L of product.
Carton box containing 1 backpack containing 2.5L of product and 1 backpack containing 5L of product.
Carton box containing 3 backpacks containing 5L of product.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

The veterinary medicinal 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.

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

7. MARKETING AUTHORISATION NUMBER

Vm 50146/4018

8. DATE OF FIRST AUTHORISATION

20 February 2003

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

December 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 23 April 2025