

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label 1 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Endofluke 100 mg/ml Oral Suspension
Triclabendazole

2. STATEMENT OF ACTIVE SUBSTANCE

<u>Active substance:</u>	<u>per/ml</u>
Triclabendazole	100 mg

<u>Excipients:</u>	
Methyl Parahydroxybenzoate	2 mg (preservative)
Propyl Parahydroxybenzoate	0.2 mg (preservative)

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

1 L

5. TARGET SPECIES

Cattle and sheep

6. INDICATIONS

7. METHOD AND ROUTES OF ADMINISTRATION

Shake container well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle and sheep (meat and offal): 56 days

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.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Protect from frost.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4018

17. MANUFACTURER’S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label 2.5 L, 5 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Endofluke 100 mg/ml Oral Suspension
Triclabendazole

2. STATEMENT OF ACTIVE SUBSTANCE

<u>Active substance:</u>	<u>per/ml</u>
Triclabendazole	100 mg

<u>Excipients:</u>	
Methyl Parahydroxybenzoate	2 mg (preservative)
Propyl Parahydroxybenzoate	0.2 mg (preservative)

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

2.5 L
5 L

5. TARGET SPECIES

Cattle and sheep

6. INDICATIONS

7. METHOD AND ROUTES OF ADMINISTRATION

Shake container well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle and sheep (meat and offal): 56 days

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.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Protect from frost.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet. Do not contaminate ponds, waterways or ditches with the product or used container.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4018

17. MANUFACTURER'S BATCH NUMBER
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Lot:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton 1 L, 6 L (5 & 1 L), 7.5 L (5 & 2.5 L), 15 L (3 x 5 L)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Endofluke 100 mg/ml Oral Suspension
Triclabendazole

2. STATEMENT OF ACTIVE SUBSTANCE

<u>Active substance:</u>	<u>per/ml</u>
Triclabendazole	100 mg

<u>Excipients:</u>	
Methyl Parahydroxybenzoate	2 mg (preservative)
Propyl Parahydroxybenzoate	0.2 mg (preservative)

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

1 L
6 L (5 L & 1 L)
7.5 L (5L & 2.5L)
15 L (3 X 5 L)

5. TARGET SPECIES

Cattle and sheep

6. INDICATIONS

7. METHOD AND ROUTES OF ADMINISTRATION

Shake container well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle and sheep (meat and offal): 56 days

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.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Protect from frost.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet. Do not contaminate ponds, waterways or ditches with the product or used container.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4018

17. MANUFACTURER'S BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

**PACKAGE LEAFLET:
Endofluke 100 mg/ml Oral Suspension**

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Endofluke 100 mg/ml Oral Suspension
Triclabendazole

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

<u>Active substance:</u>	<u>per/ml</u>
Triclabendazole	100 mg

<u>Excipients:</u>	<u>per/ml</u>
Methyl Parahydroxybenzoate	2 mg (preservative)
Propyl Parahydroxybenzoate	0.2 mg (preservative)

A white to off-white suspension.

4. INDICATIONS

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

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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 side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle and sheep

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

For single oral administration only using properly calibrated dosing equipment. The product is given as an oral drench and is suitable for most types of automatic drenching guns.

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

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

DOSAGE TABLE FOR CATTLE AND SHEEP:

CATTLE 6 ml per 50kg bodyweight		SHEEP 1 ml per 10kg bodyweight	
Animal Weight	Dose of product	Animal Weight	Dose of product
50kg	6ml	10kg	1ml
100kg	12ml	20kg	2ml
150kg	18ml	30kg	3ml
200kg	24ml	40kg	4ml
250kg	30ml	50kg	5ml
300kg	36ml	60kg	6ml
350kg	42ml	For each additional 10kg	1ml
400kg	48ml		
For each additional 50kg	6ml		

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible. The 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.

9. **ADVICE ON CORRECT ADMINISTRATION**

10. **WITHDRAWAL PERIODS**

Cattle and sheep (meat and offal): 56 days

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.

11. **SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Protect from frost.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

12. **SPECIAL WARNINGS**

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 an under-estimation 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 these 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 *Fasciola hepatica* and recommendations on how to limit further selection for resistance to anthelmintics.

Only use for liver fluke strains susceptible to triclabendazole.
If inefficacy is suspected, seek veterinary advice.

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 veterinary medicinal product to animals:

Wash hands and exposed skin before meals and after use.

When using, do not eat, drink or smoke.

Wash splashes from eyes and skin immediately.

Take off immediately any contaminated clothing.

Pregnancy, lactation or lay:

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' section).

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose (symptoms, emergency procedures, 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.

Incompatibilities:

None known.

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2021

15. OTHER INFORMATION

Available in 1 L, 2.5 L, 5 L, 6 L (5 L + 1 L), 7.5 L (5 L + 2.5 L) and 15 L (3 x 5 L) pack size.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved: 14/10/21

A handwritten signature in black ink that reads "D. Austin". The signature is written in a cursive style with a horizontal line extending to the right from the end of the name.