SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Triclafas Drench 5% w/v Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Triclabendazole 5% w/v

Excipients:
Propyl Parahydroxybenzoate 0.04% w/v (as preservative)
Methyl Parahydroxybenzoate 0.11% w/v (as preservative)

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral suspension
A white to off-white suspension

4. CLINICAL PARTICULARS

4.1 Target species

Sheep

4.2 Indications for use, specifying the target species

The product is a flukicide for the specific treatment and control of the liver fluke (*Fasciola hepatica*) infections in sheep. When used at the recommended dose rate, the product is effective against all stages of triclabendazole susceptible *Fasciola hepatica* from 2 day old early immature forms to adult fluke.

4.3 Contraindications

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

4.4 Special Warnings for each target species

Should not be used in sheep less than 7 weeks old
Care should be taken to avoid the following practises 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.

- Underdosing which may be due to underestimation 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 *Fasciola* species in small ruminants in a number of countries, including the EU. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of trematodes and recommendations on how to limit further selection for resistance to anthelmintics.

Reduction of snail populations
In addition to therapeutic dosing of animals it is advisable to take measures to reduce the population of the mud snail, *Lymnea truncatula* which acts as the intermediate host for *Fasciola hepatica* (liver fluke). This can be achieved by improving drainage. Alternatively, fencing-off wet areas where snails are prevalent, for example around streams or ponds, will prevent sheep grazing areas of high snail burdens.

4.5 Special precautions for use

i. Special precautions for use in animals

Only use for liverfluke strains susceptible to triclabendazole. Care must be taken not to damage the mouth or pharyngeal region when dosing. Clean drenching equipment before and after use. Shake container before use. Use unaltered product from the original container.

ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals

When using the product do not eat, drink or smoke. Wash splashes from eyes and skin immediately. Take off any contaminated clothing immediately. Wash hands and exposed skin before meals and after work.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

The product can be safely given to pregnant sheep.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

The product is given as an oral drench and is suitable for use through most types of automatic drenching guns. Shake the container thoroughly before use. 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.
To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosage device should be checked.
Do not mix with other products.

Recommended dose rate: 10 mg triclabendazole per kilogram bodyweight i.e. 1ml of the product per 5kg bodyweight

Example:

Bodyweight	Dosage	**Bodyweight**	**Dosage**
Up to 10 kg	2 ml	31 - 40 kg	8 ml
10 - 15 kg	3 ml	41- 50 kg	10 ml
16 - 20 kg	4 ml	51 - 60 kg	12 ml
21 - 30 kg		6 ml	

For each additional 5kg add 1ml to dose.

DOSING PROGRAMME:
The timing for treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing programme should be established by a veterinary professional.
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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Triclafas Drench is well tolerated at five times the recommended dose rate.
Triclabendazole overdosage may produce transient inappetance and loss of bodyweight.

4.11 Withdrawal period

Sheep (meat & offal) – 56 days
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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, benzimadazoles and related substances.

ATC Vet Code: QP52AC01

5.1 Pharmacodynamic properties

The product contains triclabendazole, a benzimidazole anthelmintic used in food animals, it differs from other benzimidazoles in that it is narrow spectrum. The drug accumulates significantly in both immature and adult stages of *Fasciola hepatica*

and stimulates the major routes of the parasite energy generating system, as demonstrated by glucose derived acetate and propionate formation. However, under these conditions the parasites 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 dependent on microtubular functions. The precise molecular mode of action of this fasciolicidal drug remains to be elucidated.

5.2 Pharmacokinetic properties

After oral administration, triclabendazole is rapidly metabolised to its sulphoxide and sulphone metabolites. The sulphoxide is thought to be the active moiety. In sheep the sulphoxide and sulphone metabolites reached a Cmax of approximately 10 µg/ml and 7 µg/ml at 29 hours and 48 hours, respectively. The vast majority of oral dose triclabendazole is eliminated in faeces after 7 days. Urinary excretion is minimal.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propyl Parahydroxybenzoate
Methyl Parahydroxybenzoate
Microcrystalline Cellulose and Carboxymethyl Cellulose Sodium (89:11 ratio)
Povidone K30
Sodium Phosphate Dihydrate
Simethicone
Phosphoric Acid 85% w/w (for pH adjustment)
Purified Water

6.2 Incompatibilities

None known

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 25°C.
Protect from freezing.

6.5 Nature and composition of immediate packaging

1 litre, 2.5 litre and 5 litre white, opaque, high density, flat bottomed polyethylene flexipack with white polypropylene screw fit cap and induction seal. The use orientation is inverted.
Not all pack sizes may be marketed

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
Do not contaminate ponds, waterways or ditches with the product or used container.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down, BT35 6JP

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4247

9. DATE OF RENEWAL OF THE AUTHORISATION

Date: 6 January 2011

10. DATE OF REVISION OF THE TEXT

Date: March 2013

Approved: 04 April 2013