Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasifree 10% w/v Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance

Triclabendazole	100 mg

Excipients

Methyl Parahydroxybenzoate (E218) Ph.Eur.	2.0 mg	(preservative)
Propyl Parahydroxybenzoate (E216) Ph.Eur.	0.2 mg	(preservative)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.
A white to off-white oral suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and Sheep.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

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

4.4 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.
- Underdosing, 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 triclabendazolehas 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.

4.5 Special precautions for use

Special precautions for use in animals
Careful estimation of bodyweight should be made.

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

Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with your Veterinary Surgeon.

Only use for liver fluke strains susceptible to triclabendazole.

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.

Special precautions to be taken by the person administering the veterinary medicineal 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.

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

4.6 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.

4.7 Use during pregnancy, lactation or lay

The product is safe for use during pregnancy and lactation. However, the product is not permitted for use during lactation inanimals producing milk for human consumption. See section 4.11.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

For oral administration only using properly calibrated dosing equipment.
Shake the container before use.
Use unaltered from original container.
Clean drenching equipment before and after use.

Dosage:
Fasifree is given as an oral drench and is suitable for most types of automatic drenching guns.Fasifree can safely be given to young, pregnant or stressed cattle. The recommended dose rate is 12 mg triclabendazole per kg bodyweight in cattle and 10 mg triclabendazole per kg bodyweight in sheep.

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

Animal weight	Dose of Fasifree 10%
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 addition 50 kg	6 ml

Practical Dosage Guide: Sheep: 1ml per 10 kg bodyweight.

Animal weight	Dose of Fasifree 10%
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 addition 10 kg	1 ml

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.
The same treatment dates should be used for cattle and sheep when a liver fluke dosing programme is implemented and they are grazing the same pasture concurrently.
An early spring treatment accompanied by summer treatments may prevent the flukes entering the lymnaeid snail as intermediate hosts and so the life cycle can be broken. A lasting result, however, can only be expected by involving all potential hosts (domestic ruminants, horse, game animals) in an extensive control programme.

DOSING PROGRAMME
On land where sheep are being treated according to the preventative programme and where cattle are also grazing these areas, Fasifree 10% should be administered to the cattle on the same treatment dates as the sheep. All animals should be treated on the same day.

TREATMENT TIMES

Jan	**Feb**	**Mar**	**Apr**	**May**	**Jun**
Dose			Dose		Dose
Jul	**Aug**	**Sept**	**Oct**	**Nov**	**Dec**
	Dose			Dose	

These treatments times are guidelines and should be customised under veterinary advice for each individual farm. Spring/Summer treatments prevent the flukes entering the mud snail and so the life cycle is broken.

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.

Cattle Advice:

Bought in cattle: All bought in animals, suspected to be infected with liver fluke, should be dosed before joining the main herd.

Housed cattle: Dose in the autumn or shortly after housing. Dosing is recommended before pasturing in order to prevent contamination of the pasture with liver fluke eggs.

Acute outbreaks: All animals should be treated immediately after diagnosis of acute fascioliasis.

Sheep Advice:

Areas of heavy fluke infection: Under veterinary advice, 3 Spring/Summer treatments should be administered with an extra treatment in November. Where stock wintered outside, another dose in January may be required. All bought in animals should be dosed before joining the main flock.

Areas of average/low fluke infection: Dose all sheep on fluke infected pastures at regular intervals of 10 weeks throughout the fluke season, usually from September to January/February. Guidance from the Department of Agriculture fluke forecast may be useful when deciding to start treatment. All bought in animals should be dosed before joining the main flock.

Treatment of acute outbreaks: The flock should be treated immediately after diagnosis and veterinary advice should be sought for subsequent dosing intervals. If a preventative fluke dosing programme is employed, the occurrence of acute fluke is greatly reduced.

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

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.

4.11 Withdrawal period(s)

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 and offal): 55days.

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.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics; Benzimidazoles and related substances.
ATC Vet code: QP52AC01.

5.1 Pharmacodynamic properties

The mode of action of triclabendazole is not known but is probably different from that of other benzimidazoles as it does not exert its activity by association with tubulin. Triclabendazole and its sulfoxide metabolite are anthelmintically active.

5.2 Pharmacokinetic particulars

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 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 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Xanthan Gum (E 451)
Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)
Citric Acid Anhydrous
Sodium Citrate
Polysorbate 80
Silica Colloidal Anhydrous
Simethicone emulsion
Water Purified

6.2 Major 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

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

1 litre, 2.5 litre and 5 litre high density polyethylene flat bottom back pack containers containing a white to off-white smooth suspension. The closures used for all pack sizes are 38 mm polypropylene standard caps with an induction heat seal liner. A 38 mm polypropylene spouted cap is also provided with each pack size for dispensing purposes.

Not all pack sizes may be marketed.

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

The product may have toxic effects on fish and aquatic invertebrates. Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2, 3 & 4 Airton Close
Airton Road
Tallaght
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22033/020/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 February 2002
Renewal of the last authorisation: 21 February 2007

10 DATE OF REVISION OF THE TEXT

May 2019