PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Triclafas Drench 5% w/v Oral Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Triclabendazole 5% w/v

3. PHARMACEUTICAL FORM

An off-white to white oral suspension

4. PACKAGE SIZE

1 litre, 2.5 litres, 5 litres.

5. TARGET SPECIES

Sheep

6. INDICATION(S)

Triclafas Drench 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 Triclafas Drench is effective against all stages of triclabendazole susceptible *Fasciola hepatica* from 2 day old early immature forms to adult fluke.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Triclafas Drench is given as an oral drench and is suitable for use through most types of automatic drenching guns.
To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Shake the container thoroughly before use.
Do not mix with other products
Use unaltered product from the original container.
Clean drenching equipment before and after use.
Recommended dose rate: 10 mg triclabendazole per kilogram bodyweight i.e. 1ml Triclafas Drench per 5kg bodyweight. For each additional 5kg add 1ml to dose.

Examples:

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		

DOSING PROGRAMME:

The timing for treatment should be based on epidemiological factors and should be customised to 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 body weight and dosed accordingly, in order to avoid under or overdosing.

8. WITHDRAWAL PERIOD

Sheep (meat & offal) – 56 day
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 WARNING(S), IF NECESSARY

Do not use in cases of known hypersensitivity to triclabendazole.

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 (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.
Should not be used in sheep less than 7 weeks old.

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.

USER WARNINGS:

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 work.

10. EXPIRY DATE

DOM.:
EXP.:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from freezing. Keep container in outer carton.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority. 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

POM-VPS

To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Licence Holder and Manufacturer:
Norbrook Laboratories Limited
Newry
Co. Down
Northern Ireland

Distributed by:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
BT35 6QQ
Co Down
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4247

17. MANUFACTURER'S BATCH NUMBER

B.N.:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Triclafas Drench 5% w/v Oral Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Triclabendazole 5%w/v

3. PHARMACEUTICAL FORM

An off-white to white oral suspension

4. PACKAGE SIZE

1 L / 2.5 L / 5 L

5. TARGET SPECIES

Sheep

6. INDICATION(S)

Triclafas Drench 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 Triclafas Drench is effective against all stages of triclabendazole susceptible *Fasciola hepatica* from 2 day old early immature forms to adult fluke.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage Guide:
Triclafas Drench is given as an oral drench and is suitable for use through most types of automatic drenching guns.
To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.
Do not mix with other products.

Recommended dose rate: 10 mg triclabendazole per kilogram bodyweight i.e. 1ml Triclafas Drench per 5kg bodyweight. For each additional 5kg add 1ml to dose.

Example:

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

DOSING PROGRAM – The timing for treatment should be based on epidemiological factors and should be customized 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 over dosing.

Keep the container in the outer carton.

8. 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.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in cases of known hypersensitivity to triclabendazole.

Intensive use or misuse of anthelmintics can give rise to resistance.

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 (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.

To reduce this risk, dosing programmes should be discussed with your Veterinary Surgeon. Efficacy of this product against liver fluke is reduced if triclabendazole-resistant strains are present.

Should not be used in sheep less than 7 weeks old.

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

USER WARNINGS:

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 work.

10. EXPIRY DATE

D.O.M.:
Exp.:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from freezing. Keep container in outer carton

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority. 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

POM-VPS

To be supplied only on veterinary prescription

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Licence Holder and Manufacturer:
Norbrook Laboratories Limited
Newry
Co. Down
Northern Ireland

Distributed By:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
BT35 6QQ
Co Down
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4247

17. MANUFACTURER’S BATCH NUMBER

B.N.:

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}

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

Licence Holder and Manufacturer:
Norbrook Laboratories Limited
Newry
Co. Down
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Triclafas Drench 5% w/v Oral Suspension

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Triclabendazole 5%w/v

4. PHARMACEUTICAL FORM

An off-white to white oral suspension

5. PACKAGE SIZE

6. INDICATION(S)

Triclafas Drench 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 Triclafas Drench is effective against all stages of triclabendazole susceptible *Fasciola hepatica* from 2 day old early immature forms to adult fluke.

7. CONTRAINDICATIONS

8. ADVERSE REACTIONS

9. TARGET SPECIES

Sheep

10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage Guide:
Triclafas Drench is given as an oral drench and is suitable for use through most types of automatic drenching guns.
To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.
Do not mix with other products.

Recommended dose rate: 10 mg triclabendazole per kilogram bodyweight i.e. 1ml Triclafas Drench per 5kg bodyweight. For each additional 5kg add 1ml to dose.

Example:

Bodyweight (kg)	**Dose**
Up to 10 kg	2 ml
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16 - 20 kg	4 ml
21 - 30 kg	6 ml
31 - 40 kg	8 ml
41- 50 kg	10 ml
51 - 60 kg	12 ml

DOSING PROGRAM – The timing for treatment should be based on epidemiological factors and should be customized 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 over dosing.

Keep the container in the outer carton.

11. ADVICE ON CORRECT ADMINISTRATION

12. 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.

13. SPECIAL STORAGE PRECAUTIONS
Keep the container in the outer carton.
[Pharmaceuticals ONLY - *The following statement should be included if there is an in-use shelf life (example: solution for injection)]*
<When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.>

14. SPECIAL WARNING(S)<User Warnings>
Do not use in cases of known hypersensitivity to triclabendazole.

Intensive use or misuse of anthelmintics can give rise to resistance.

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 (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.

To reduce this risk, dosing programmes should be discussed with your Veterinary Surgeon. Efficacy of this product against liver fluke is reduced if triclabendazole-resistant strains are present.

Should not be used in sheep less than 7 weeks old.

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

USER WARNINGS:
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 work.

15. EXPIRY DATE

D.O.M.:
Exp.:

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority. Do not contaminate ponds, waterways or ditches with the product or used container.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

October 2022

18. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

FOR ANIMAL TREATMENT ONLY

POM-VPS

To be supplied only on veterinary prescription

19. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

20. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4247

21. MANUFACTURER'S BATCH NUMBER

B.N.:

22. OTHER INFORMATION

Distributed By:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
BT35 6QQ
Co Down
Northern Ireland

Approved 28 October 2022