PARTICULARS TO APPEAR ON LABEL (no leaflet)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tectomec 0.8 mg/ml Oral Solution Drench for Sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Tectomec Drench is an Oral solution containing 0.8 mg/ml ivermectin

3. PHARMACEUTICAL FORM

Oral Solution

4. PACKAGE SIZE

1L/2.5L/5L/2x5 Litres
200/500/1000/2000 doses for 20kg lambs
80/200/400/800 doses for 50kg ewes

5. TARGET SPECIES

Sheep

6. INDICATION(S)

Broad spectrum endectocide for the treatment and control of gastrointestinal nematodes, lungworms and nasal bots in sheep.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration only.
Do not mix with other products.

Sheep: 2.5 ml per 10kg bodyweight (200µg ivermectin per kg bodyweight) to be given orally.

	PRACTICAL DOSAGE RECOMMENDATIONS (Sheep above 60kg should be given a further 2.5 ml for each additional 10kg bodyweight)					
Weight of Sheep	10 kg	20 kg	30 kg	40 kg	50 kg	60 kg
Dose	2.5 ml	5 ml	7.5 ml	10 ml	12.5 ml	15 ml

Estimate bodyweight accurately prior to dosing. It is recommended that a suitably calibrated dosing gun is used to allow accurate dosing, especially in young animals.

8. WITHDRAWAL PERIOD

Sheep must not be slaughtered for human consumption during treatment.
Sheep (Meat): 14 days
Do not use in sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in species other than sheep
The product has been formulated specifically for use in sheep. It should not be used in other species as severe adverse reactions, including fatalities in dogs, may occur.
Not for intravenous or intramuscular use. Some animals may cough slightly immediately after treatment. This is a temporary occurrence and of no clinical consequence.

Operator Warnings:
Do not smoke, drink or eat while handling this product.
Wash hands after use.
Avoid contact with skin and eyes. In cases of accidental eye or skin contact, wash the affected area with clean running water immediately. Seek medical attention if irritation persists.

10. EXPIRY DATE

<EXP {month/year}>

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC. Protect from direct sunlight. Keep the container in the outer carton.

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

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. 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 containers.

Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, discuss the dosing programmes with your veterinary surgeon.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only.

POM-VPS

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

Manufactured by:
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)

ManA 2000
VM: 02000/4198

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

DOM:

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

For further information on uses and dosing, please refer to the carton.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tectomec 0.8 mg/ml Oral Solution Drench for Sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Tectomec Drench is an Oral solution containing 0.8 mg/ml ivermectin

3. PHARMACEUTICAL FORM

Oral Solution

4. PACKAGE SIZE

1 L / 2 L / 2.5 L / 2 X 5 LITRE

5. TARGET SPECIES

Sheep

6. INDICATION(S)

The product is a broad spectrum endectocide for the treatment and control of gastrointestinal nematodes, lungworms and nasal bots in sheep:

Gastrointestinal worms: Adult and immature forms of *Haemonchus contortus, Ostertagia (Teladorsagia) circumcincta, Trichostrongylus* spp, *Cooperia* spp, *Nematodirus* spp including *N. battus, Strongyloides papillosus, Oesophagostomum* spp, and adult *Chabertia ovina*.

Inhibited larval stages and benzimidazole-resistant strains of *Haemonchus contortus* and *Ostertagia (Teladorsagia) circumcincta* are also controlled.

Lungworms: Adult and immature forms of *Dictyocaulus filaria*.

Nasal bots: All larval stages of *Oestrus ovis*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration only.

Do not mix with other products

Sheep: 2.5 ml per 10kg bodyweight (200µg ivermectin per kg bodyweight) to be given orally (see table).

WEIGHT OF SHEEP

(Sheep above 60 kg should be given a further 2.5 ml for each additional 10 kg bodyweight)

Number of sheep to be treated	10 kg	20 kg	30 kg	40 kg	50 kg	60 kg
1	2.5 ml	5 ml	7.5 ml	10 ml	12.5 ml	15 ml
10	25 ml	50 ml	75 ml	100 ml	125 ml	150 ml
50	125 ml	250 ml	375 ml	500 ml	625 ml	750 ml
100	250 ml	500 ml	750 ml	1 litre	1.25 litres	1.5 litres
500	1.25 litres	2.5 litres	3.75 litres	5 litres	6.25 litres	7.5 litres
1000	2.5 litres	5 litres	7.5 litres	10 litres	12.5 litres	15 litres
No. of doses 1L / 2.5L / 5L / 10 Litres provides	400 /1000 /2000 /4000 doses	200 / 500 /1000 /2000 doses	133.3 /333.25 /666.5 / 1333 doses	100 /250 /500 /1000 doses	80 /200 /400 /800 doses	66.6 /166.5 /333 /666 doses

Estimate bodyweight accurately prior to dosing. It is recommended that a suitably calibrated dosing gun is used to allow accurate dosing, especially in young animals. The product can be administered to ewes at any stage of pregnancy or lactation provided that the milk is not used for human consumption. It can be given to all ages of animals including young lambs.

1 L	2.5 L	5 L	2 x 5 L
200 doses for 20kg lambs	500 doses for 20kg lambs	1000 doses for 20kg lambs	2000 doses for 20kg lambs
80 doses for 50kg ewes	200 doses for 50kg ewes	400 doses for 50kg ewes	800 doses for 50kg ewes

8. WITHDRAWAL PERIOD

Sheep must not be slaughtered for human consumption during treatment.
Sheep (Meat): 14 days
Do not use in sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in species other than sheep

The product has been formulated specifically for use in sheep. It should not be used in other species as severe adverse reactions, including fatalities in dogs, may occur.

Not for intravenous or intramuscular use. Some animals may cough slightly immediately after treatment. This is a temporary occurrence and of no clinical consequence.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, discuss the dosing programmes with your veterinary surgeon.

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 ivermectin (an avermectin) has been reported in *Teladorsagia* in sheep and goats within the EU and it is common in *Haemonchus* in sheep outside the EU. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematode and recommendations on how to limit further selection for resistance to anthelmintics.

Operator Warnings:

Do not smoke, drink or eat while handling this product.

Wash hands after use.

Avoid contact with skin and eyes. In cases of accidental eye or skin contact, wash the affected area with clean running water immediately. Seek medical attention if irritation persists.

10. EXPIRY DATE

<EXP {month/year}>

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC. Protect from direct sunlight. Keep the container in the outer carton

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

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. 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 containers.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only.

POM-VPS

To be supplied only on veterinary prescription

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

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17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

Further Information:

Class of anthelmintic endectocides:

3-AV

Instructions for use with automatic dosing equipment:

1. Remove the product container from the carton and shake well.
2. Attach plastic hook through a hole at the base of the bottle and tie strap through diagonally opposite hole at the top, making adjustments as necessary to allow the bottle to hang comfortably on the operator's back.
3. With the product container in the upright position, remove the plain cap and pierce seal with the nozzle cap provided.
4. Screw nozzle cap tightly onto the bottle and firmly attach tube from the automatic dosing equipment to the nozzle.
5. Hang the bottle in the inverted position on the operator's back and carefully prime the gun.

Part used packs may be kept. The nozzle cap should be replaced by the plain cap.

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

LOGO

Approved 28 October 2022