PARTICULARS TO APPEAR ON THE OUTER PACKAGE 250 ML, 1 LITRE, 2.5 LITRE, 5 LITRE CARTONS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tectomec 5 mg/ml Pour-on Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ivermectin 5 mg/ml

3. PHARMACEUTICAL FORM

Pour-on Solution

4. PACKAGE SIZE

250 ml
1 litre
2.5 litre
5 litre

5. TARGET SPECIES

Beef and non-lactating dairy cattle.

6. INDICATION(S)

The product is indicated for the effective treatment and control of the following gastrointestinal roundworms, lungworms, warbles, chorioptic and sarcoptic mange and sucking and biting lice in beef cattle and non-lactating dairy cattle.

Gastrointestinal roundworms (adult and fourth stage larvae)
Ostertagia ostertagi (including inhibited *O. ostertagi*), *Haemonchus placei, Trichostrongylus axei, Trichostrongylus colubriformis, Cooperia spp*., *Oesophagostomum radiatum, Strongyloides papillosus* (adult), *Trichuris spp* (adult).

Lungworms (adults and fourth stage larvae)
Dictyocaulus viviparus.

Warbles (parasitic stages)
Hypoderma bovis, Hypoderma lineatum

Lice
Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus, Damalinia bovis.

Mange mites
Chorioptes bovis, Sarcoptes scabiei var bovis.

The product given at the recommended dose of 500 micrograms Ivermectin per kg bodyweight controls infections with *Trichostrongylus axei* and *Cooperia* spp acquired

up to 14 days after treatment. *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired up to 21 days after treatment and *Dictyocaulus viviparous* acquired up to 28 days after treatment. It also controls horn flies (*Haematobia irritans*) for up to 35 days after treatment.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pour-on solution

Read the package leaflet before use.

Ivermectin should be administered topically at 500 µg/kg b.w. (1 ml/10 kg b.w.).

The formulation should be applied topically along the mid-line of the back in a narrow strip between the withers and tailhead.

8. WITHDRAWAL PERIOD

Cattle (meat): 28 days
Not for use in cows producing milk for human consumption.
Do not use in non-lactating dairy cows, including pregnant heifers, within 60 days of calving.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 30 °C
Store in the original container
Close container when not in use and store in an upright position.
Keep upright when filling and during storage.
Keep the bottle in the outer carton.
Protect from light.
No smoking.
Keep away from sources of ignition.

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

Disposal: read package leaflet

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"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP
Northern Ireland

Distributed by:
Norbrook Laboratories (GB) Limited,
1 Saxon Way East,
Oakley Hay Industrial Estate,
Corby, Northamptonshire,
NN18 9EX,
United Kingdom.

16. MARKETING AUTHORISATION NUMBER

ManA 2000
Vm 02000/4394

17. MANUFACTURER'S BATCH NUMBER

B.N.:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE:

250 ML, 1 LITRE, 2.5 LITRE, 5 LITRE CARTONS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tectomec 5 mg/ml Pour-on Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ivermectin 5 mg/ml

3. PHARMACEUTICAL FORM

Pour-on Solution

4. PACKAGE SIZE

250 ml
1 litre
2.5 litre
5 litre

5. TARGET SPECIES

Beef and non-lactating dairy cattle.

6. INDICATION(S)

The product is indicated for the effective treatment and control of the following gastrointestinal roundworms, lungworms, warbles, chorioptic and sarcoptic mange and sucking and biting lice in beef cattle and non-lactating dairy cattle.

Gastrointestinal roundworms (adult and fourth stage larvae)
Ostertagia ostertagi (including inhibited *O. ostertagi*), *Haemonchus placei, Trichostrongylus axei, Trichostrongylus colubriformis, Cooperia spp*., *Oesophagostomum radiatum, Strongyloides papillosus* (adult), *Trichuris spp* (adult).

Lungworms (adults and fourth stage larvae)
Dictyocaulus viviparus.

Warbles (parasitic stages)
Hypoderma bovis, Hypoderma lineatum

Lice
Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus, Damalinia bovis.

Mange mites
Chorioptes bovis, Sarcoptes scabiei var bovis.

The product given at the recommended dose of 500 micrograms Ivermectin per kg bodyweight controls infections with *Trichostrongylus axei* and *Cooperia* spp acquired up to 14 days after treatment. *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired up to 21 days after treatment and *Dictyocaulus viviparous* acquired up to 28 days after treatment. It also controls horn flies (*Haematobia irritans*) for up to 35 days after treatment.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pour-on solution

Read the package leaflet before use.

Ivermectin should be administered topically at 500 µg/kg b.w. (1 ml/10 kg b.w.).

The formulation should be applied topically along the mid-line of the back in a narrow strip between the withers and tailhead.

8. WITHDRAWAL PERIOD

Cattle (meat): 28 days
Not for use in cows producing milk for human consumption.
Do not use in non-lactating dairy cows, including pregnant heifers, within 60 days of calving.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 1 year.

11. SPECIAL STORAGE CONDITIONS

Do not store above 30 °C.
Store in the original container.
Close container when not in use and store in an upright position.
Keep upright when filling and during storage.
Keep the bottle in the outer carton.
Protect from light.
No smoking.
Keep away from sources of ignition.

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

Disposal: read package leaflet

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"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Newry
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BT35 6JP
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Distributed by:
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Corby, Northamptonshire,
NN18 9EX,
United Kingdom.

16. MARKETING AUTHORISATION NUMBER

ManA 2000
Vm 02000/4394

17. MANUFACTURER'S BATCH NUMBER

B.N.:

PACKAGE LEAFLET FOR:

Tectomec 5 mg/ml Pour-on Solution

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:

Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tectomec 5 mg/ml Pour-on Solution
Ivermectin

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

Ivermectin 5 mg/ml

4. INDICATION(S)

The product is indicated for the effective treatment and control of the following gastrointestinal roundworms, lungworms, warbles, chorioptic and sarcoptic mange and sucking and biting lice in beef cattle and non-lactating dairy cattle.

Gastrointestinal roundworms (adult and fourth stage larvae)
Ostertagia ostertagi (including inhibited *O. ostertagi*), *Haemonchus placei, Trichostrongylus axei, Trichostrongylus colubriformis, Cooperia* spp., *Oesophagostomum radiatum*, *Strongyloides papillosus* (adult), *Trichuris* spp (adult).

Lungworms (adults and fourth stage larvae)
Dictyocaulus viviparus.

Warbles (parasitic stages)
Hypoderma bovis, *Hypoderma lineatum*.

Lice
Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus, Damalinia bovis.

Mange mites
Chorioptes bovis, Sarcoptes scabiei var bovis.

The product given at the recommended dose of 500 micrograms Ivermectin per kg bodyweight controls infections with *Trichostrongylus axei* and *Cooperia* spp acquired up to 14 days after treatment. *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired up to 21 days after treatment and *Dictyocaulus viviparous* acquired up to 28 days after treatment. It also controls horn flies (*Haematobia irritans*) for up to 35 days after treatment.

5. CONTRAINDICATIONS

Do not treat cattle when their hair or hide is wet. Do not treat cattle if rain is expected, as rain within two hours of treatment may reduce efficacy. Do not apply to areas of skin which have mange, scabs or other lesions or to areas contaminated with mud or manure.

The product has been formulated for specific use in cattle. Do not apply or administer to other species, as severe reactions, including fatalities in dogs, may occur.

6. ADVERSE REACTIONS

None are expected when used at the recommended dose rate.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Beef and non-lactating dairy cattle.

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

Ivermectin should be administered topically at 500 µg/kg b.w. (1 ml/10 kg b.w.).

To ensure administration of a correct dose, body weight 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 over dosing.

The formulation should be applied along the midline of the back in a narrow strip between the withers and the tailhead.

The timing of treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing program should be established by a qualified professional person.

9. ADVICE ON CORRECT ADMINISTRATION

If stored at temperatures below 0ºC the product may appear cloudy. If the product is brought back to room temperature the normal appearance will be restored without affecting efficacy.

10. WITHDRAWAL PERIOD(S)

Cattle (meat): 28 days
Not for use in cows producing milk for human consumption.
Do not use in non-lactating dairy cows, including pregnant heifers, within 60 days of calving.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 30°C.
Store in the original container.
Keep the container in the outer carton
Keep the container tightly closed.
Protect from light.
Close container when not in use and store in an upright position.
Keep upright when filling and during storage.
No smoking.
Keep away from sources of ignition.

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.

Shelf life after first opening the container: 1 year

12. SPECIAL WARNING(S)

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, (if any).

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

Highly flammable – keep away from heat, sparks, open flame or other sources of ignition.

The product may be irritating to human skin and eyes and the user should be careful not to apply it to himself or other persons. Operators should wear nitrile rubber gloves and boots with a waterproof coat when applying the product. Protective clothing should be washed after use. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and seek medical attention.

Do not eat, drink or smoke while handling the product. Wash hands after use. Use only in well ventilated areas or outdoors.

Pregnancy & Lactation: The product can be safely administered to cows during pregnancy or lactation

Interaction with other medicinal products and other forms of interaction: None known.

Overdose (symptoms, emergency procedures, antidotes): No signs of toxicity are likely up to 5 mg/kg (ten times the recommended dose rate). There is no known antidote.

Incompatibilities: None known.

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

IVERMECTIN IS EXTREMELY DANGEROUS TO AQUATIC LIFE.

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

Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2018

15. OTHER INFORMATION

250 ml, 1 litre, 2.5 litre, 5 litre

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.

ManA 2000
Vm 02000/4394

For animal treatment only

POM-VPS

To be supplied only on veterinary prescription

Distributed by:
Norbrook Laboratories (GB) Limited,
1 Saxon Way East,
Oakley Hay Industrial Estate,
Corby, Northamptonshire,
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United Kingdom.

Approved: 17 April 2018