SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tectomec 5 mg/ml Pour on Solution

2. QUALITATIVE & QUANTITATIVE COMPOSITION

Each ml contains:

Active substance

Ivermectin	5 mg

Excipients

Patent Blue V (E131)	0. 005 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Pour-on solution
Clear blue liquid

4. CLINICAL PARTICULARS

4.1 Target species

Beef and non-lactating dairy cattle.

4.2 Indications for use

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 viviparus* acquired up to 28 days after treatment. It also controls horn flies (*Haematobia irritans*) for up to 35 days after treatment.

4.3 Contra-indications

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.

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, (if any).

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where 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 *Cooperia oncophora* in cattle within the EU, in *Teladorsagia* in cattle in developed countries such as New Zealand and *Haemonchus* in cattle outside the EU. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance.

4.5 Special precautions for use

Special precautions for use in animals

None known.

(ii) Special precautions to be taken by the person administering the product

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.

4.6 Adverse reaction (frequency and seriousness)

None are expected when used at the recommended dose rate.

4.7 Use during pregnancy, lactation and lay

The product can be safely administered to cows during pregnancy or lactation. Also, see warnings in section 4.11 regarding withdrawal periods.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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.

4.10 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.

4.11 Withdrawal periods for the various foodstuffs including those for which the withdrawal period is zero

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ivermectin is a 22, 23-dihydro derivative of an avermectin (which is a fermentation product produced by *Streptomyces avermitilis*) and consists of two homologues: B1a and B1b. it is a parasiticide with nematocidal, insecticidal and acaricidal activity documented in a wide range of domesticated animals.

Avermectins act to stimulate GABA mediated chloride ion conductance, causing irreversible neuromuscular blockade in nematodes, followed by paralysis and death.

ATC vet code: QP54AA01

5.2 Pharmacokinetic properties

After administration of the recommended dosage to cattle varying inter-individual ivermectin plasma levels were observed with mean values of Cmax and tmax of 11.26 ng/ml and 97h, respectively.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Patent Blue V (E131)
Triethanolamine
Crodamol Cap
Isopropyl alcohol

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 1 year.

6.4 Special precautions for storage

Following withdrawal of the first dose, use the product within 1 year. Discard unused material.
Close container when not in use and store in an upright position.
Containers should be stored in their original boxes when not in use.
Keep upright when filling and during storage.
Do not store above 30°C.
If stored at temperatures below 0°C the product may appear cloudy. If the product is brought back to room temperature the normal appearance will be restored without affecting efficacy.
No smoking.
Keep away from sources of ignition.
Protect from light.
Store in tightly closed original container.

6.5 Nature and composition of immediate packaging

250 ml and 1 litre natural high density polyethylene twin-neck dispensing bottles with integrated graduated dispensing chamber.
250 ml and 1 litre natural high density polyethylene squeeze dispending bottles with integrated graduated dispensing chamber.
2.5 litre and 5 litre white low density polyethylene backpacks with polypropylene screw caps with wood pulp faced aluminium wad seal containing clear blue solution.
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

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.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4394

9. DATE OF FIRST AUTHORISATION

5 June 2000

10. DATE OF REVISION OF THE TEXT

April 2018

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