SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin Pour-on vet. 5 mg/ml, Pour-on solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
1 ml contains: ivermectin 5 mg

Excipients:
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Pour-on solution.
The solution is clear blue.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the target species

Noromectin Pour-on vet is indicated for treatment of following parasites in cattle:

Gastrointestinal round worms
Ostertagia ostertagi (adult and L4 hypobiotic larvae)
Haemonchus placei (adult and L4)
Trichostrongylus axei (adult and L4)
Trichostrongylus colubriformis (adults and L4)
Cooperia spp. (adults and L4)
Oesophagostomum radiatum (adult and L4)

Lungworms
Dictyocaulus viviparus (adult and L4)

Warbles (parasitic forms)
Hypoderma bovis
Hypoderma lineatum

Lice
Sucking lice
Linognathus vituli
Haematopinus eurysternus
Biting lice
Damalinia bovis

Mange
Chorioptes bovis
Sarcoptes scabiei var. *bovis*

Flies
Haematobia irritans

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

4.4 Special Warnings for each target species

Do not treat cattle when their hide is wet, dirty animals or animals with mange or scab lesions at the site of application, since this might reduce the effect of the product. Rain within two hours following application might also reduce the effect.

Assess bodyweight as accurately as possible before calculating the dosage.

4.5 Special precautions for use

Special precautions for use in animals

In non-target species, ivermectins/milbemycins can be less well tolerated. (Cases of intolerance with fatal consequences have been reported in dogs, particularly collies, Old English Sheepdogs and related breeds and turtles).

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

This product should only be used in well-ventilated areas or outdoors. Use protective gloves. Avoid contact to skin and eyes. If accidental contact to skin occurs wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.

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 *Cooperia oncophora* and *Ostertagia ostertagi* 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 to anthelmintics.

4.6 Adverse reactions (frequency and seriousness)

No adverse reactions has been reported at recommended dosing.

4.7 Use during pregnancy, lactation or lay

Noromectin Pour-On can be administered to beef cows and pigs at any stage of pregnancy or lactation. Noromectin Pour-On must not be administered to lactating dairy cattle, dry cows or heifers later than 60 days prior to calving, when milk is intended for human consumption.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Topical administration at a dose of 1 ml per 10 kg bodyweight (corresponding to the recommended dose of 0,5 mg per kg bodyweight). The formulation should be applied along the mid-line of the back in a narrow strip between the withers and tailhead.

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

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

No symptoms from overdosing have been reported with 10 times the recommended dose has been used (5 mg per kg bodyweight). No antidote is known.

4.11 Withdrawal period

Meat and offal: 21 days.
Lactating dairy cattle must not be treated.
Dry cows or heifers must not be treated later than 60 days before calving.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintic

ATC Vet Code: QP54AA01

5.1 Pharmacodynamic properties

Ivermectin is an endectocide, belonging to the avermectin group (macrocyclic lactones). In nerve and muscle cells of many non-vertebrates there are glutamateregulated chloride ion channels, to which the ivermectin binds selectively. This results in an increased permeability for chloride ions across the cell membrane, causing a hyper polarisation of nerve- and muscle cells in the parasite resulting in paralysis and death of the parasite. Compounds from this group can also interact with other ligand-gated chloride ion channels, for example those regulated by the neurotransmitter gamma-amino butyric acid (GABA).
Mammals do not have glutamate regulated chloride ion channels, which is the reason for the satisfactory safety margin of the macrocyclic lactones. Macrocyclic lactones also have a low affinity for other, by mammals existing ligand gated chloride ion channels and do not cross the blood-brain barrier under normal conditions.

5.2 Pharmacokinetic properties

Following local administration of Noromectin Pour-on vet, a dose corresponding to 0,5 mg per kg body weight, the average maximum plasma concentration was 11 ng/ml, which was reached after approximately 4 days. The elimination T1/2 is 8 days but shows a great variation (±63 hrs).
The substance is metabolised to a very small extent and un-metabolised ivermectin and degradation products are excreted to 98% via faeces and to 2% via urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Trolamine
Cetostearyloctanoat-mixture (isopropyl myristate, stearyl octanoate and cetyl octanoate)
Isopropylalcohol
Patent blue (EI31)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 25°C
Keep container in the outer carton in order to protect from light.
Inflammable. Keep the container tightly closed.

The containers should be stored in a stand up position. If stored below 0°C the solution may appear cloudy. Allowing to warm to room temperature will restore the normal appearance without affecting the efficacy. Do not use cloudy solution.

6.5 Nature and composition of immediate packaging

HD polyethylene containers with dispenser
Package: 250 and 1000 ml.
HD polyethylene collapsible backpack
Package: 1 L
LD polyethylene collapsible backpack
Package: 2,5 L

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

Ivermectin is extremely dangerous to fish and aquatic life. Drug containers and residual content should be disposed of safely and handed over to the Pharmacies for destruction.

7. MARKETING AUTHORISATION HOLDER

<To be completed nationally>

8. MARKETING AUTHORISATION NUMBER(S)

14987

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

2001-02-23/2006-02-23

10. DATE OF REVISION OF THE TEXT

2023-04-19

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.