SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin vet. 10 mg/ml, solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

1 ml contains:	Ivermectin 10 mg

Excipients:

Glycerolformal	0,4 ml
Macrogol 200 ad	1,0 ml

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection
Colourless to pale yellow, clear liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, pig and reindeer.

4.2 Indications for use, specifying the target species

Noromectin vet. is indicated for treatment of the following parasites by cattle, pig and reindeer:

Cattle
Gastro-intestinal roundworms (adult and fourth stage larvae, L4):
Ostertagia ostertagi (including inhibited L4)
Ostertagia lyrata
Haemonchus placei
Trichostrongylus axei
Trichostrongylus colubriformis (L4)
Cooperia oncophora
Cooperia punctata
Cooperia pectinata
Nematodirus spatiger (adult)
Oesophagostomum radiatum

Lungworms (adult and fourth stage larvae, L4):
Dictyocaulus viviparus

Warbles (larval stages)

Hypoderma bovis
Hypoderma lineatum

Mange Mites
Sarcoptes scabiei var. *bovis*
Psoroptes bovis

Lice
Linognathus vituli
Haematopinus eurysternus

Pig

Gastro-intestinal roundworms (adult and fourth stage larvae, L4):
Ascaris suum
Hyostrongylus rubidus
Oesophagostomum spp.
Strongyloides ransomi (adult)

Lungworms
Metastrongylus spp. (adult)

Mange Mites
Sarcoptes scabiei var. *suis*

Lice
Haematopinus suis

Reindeer

Larval stages of *Oedemagena tarandi*

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

Neonatal pigs are sensitive for overdosing of ivermectin, probably because of a higher permeability of the blood-brain-barrier.
Piglets <5 days should not be injected.

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

No particular.

4.6 Adverse reactions (frequency and seriousness)

Local reaction (discomfort and swelling) has been observed.

4.7 Use during pregnancy, lactation or lay

Noromectin vet. can be administered to beef cows and pigs at any stage of pregnancy or lactation. Noromectin vet. 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

Cattle and reindeer: 1 ml Noromectin vet. per 50 kg body weight, corresponding to 0,2 mg ivermectin per kg body weight injected subcutaneously.
Pigs: 1 ml Noromectin vet. per 33 kg body weight, corresponding to 0,3 mg ivermectin per kg body weight injected subcutaneously.

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

Heavy overdosing (4-30 mg/kg) may induce lethargy, ataxia and tremor.

4.11 Withdrawal period

Meat and offal: Cattle 49 days and pig and reindeer 28 days

Lactating dairy cattle must not be injected. Dry cows and heifers must not be injected later than 60 days prior to 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

Maximal serum concentration is achieved approximately 2 days after administration and elimination half-time in plasma is approximately 5 days in cattle (shorter in the pig). The substance is only partly metabolised and in tissues ivermectin is distributed in the following order:
liver>fat>kidney>muscle by cattle and fat>liver>kidney>muscle by pigs.

Non-metabolised ivermectin and intermediate products are eliminated to 98% via faeces and to 2% via urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol formal (Glycerol formal contains as stabilisers:
Thiodipropionic acid, N-propyl gallate,
Disodium edetate)
Macrogol 200

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years
After first opening: 28 days

6.4 Special precautions for storage

Do not store above 25°C.

Keep the container in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

HD polyethylene vial with bromobutyl stoppers and aluminium overseals.

Pack sizes: 50 ml, 100 ml, 250 ml, 500 ml, 6 x 250 ml.
Not all pack sizes may be marketed

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)

14895

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

2001-02-23/2006-02-23

10. DATE OF REVISION OF THE TEXT

2019-05-03

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.