

PACKAGE LEAFLET FOR:
Noromectin vet. 10 mg/ml, solution for injection
ivermectin

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION
HOLDER AND OF THE MANUFACTURING AUTHORISATION
HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

<To be completed nationally>

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin vet. 10 mg/ml, solution for injection

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

Active substance(s):

1 ml contains:
Ivermectin 10 mg

Excipient(s):

Glycerol formal	0,4 ml
(Glycerol formal contains as stabilisers: Thiodipropionic acid, N-propyl gallate, Disodium edetate)	
Macrogol 200 ad	1,0 ml

4. INDICATION(S)

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
Hyostrogylus 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*

5. CONTRAINDICATIONS

Should not be injected in animals with known hypersensitivity to ivermectins.

6. ADVERSE REACTIONS

Local reaction (discomfort and swelling) has been observed.

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

7. TARGET SPECIES

Cattle, pig and reindeer.

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

10. 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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children

Do not store above 25°C.

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

Do not use after the expiry date stated on the carton.

Shelf life after first opening: 28 days

12. SPECIAL WARNINGS

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.

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).

Pregnancy and lactation

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.

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

Free ivermectin is extremely toxic to aquatic life. Residual contents should be returned to the Pharmacies for destruction.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

2019-05-03

15. OTHER INFORMATION

Pack sizes: 50 ml, 100 ml, 250 ml, 6x250 ml, 500 ml.
Not all pack sizes may be marketed