1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enovex 5 mg/ml Pour-On Solution for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Ivermectin 5 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Crodamol CAP	
Triethanolamine	
Patent Blue V (E131) Dye	0.005 mg
Isopropyl alcohol	to 1 mL

A clear blue pour-on solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (beef and non-lactating cattle).

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, eyeworms, warbles, mites and lice.

Gastrointestinal roundworms (adults and fourth stage larvae):
Ostertagia ostertagi (including inhibited *O ostertagi*), *Haemonchus placei*, *Trichostrongylus axei*, *Trichostrongylus colubriformis*, *Cooperia* spp, *Oesophagostomum radiatum*, *Strongyloides papillosus* (adult) and *Trichuris* spp (adults). Occasionally variable activity may be observed against *H. placei* (L4), *Cooperia* spp, *T. axei* and *T. colubriformis.*

Lungworms (adult and fourth stage larvae):
Dictyocaulus viviparus

Eyeworms (adult):

Thelazia rhodesii

Warbles:
Hypoderma bovis, Hypoderma lineatum

Sucking Lice:
Linognathus vituli, Haematopinus eurysternu

Biting Lice:
Damalinia (bovicola) bovis.

Mange Mites:
Chorioptes bovis, Sarcoptes scabiei var *bovis*

3.3 Contraindications:

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

3.4 Special warnings

Care should be taken to avoid the following practices as they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelminthics from the same class, over an extended period of time.
- Underdosing which may be due to underestimation of bodyweight, misadministration of the product, or lack of calibration of the dosing device

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 tests 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 has been reported in *Osteragia ostertagi* in cattle. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about the susceptibility of this helminth species and recommendations on how to limit further selection for resistance to anthelminthics.

Do not treat cattle when their hair or hide is wet. Do not treat cattle if rain is expected, as rain within 2 hours of treatment may reduce efficacy.

3.5 Special precautions for use

Special precautions for safe use in the target species:

To avoid secondary reactions due to death of Hypoderma larvae in the oesophagus or in the spine it is recommended to administer the product at the end of the period of warble fly activity and before the larvae reach their resting sites. Consult your veterinarian on the correct timing of treatment.

Do not apply to areas of skin which have mange scabs or other lesions or to areas contaminated with mud or manure.

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

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

The veterinary medicinal product may be irritating to human skin and eyes and the user should be careful not to apply it to himself or other persons. Personal protective equipment consisting of rubber gloves and boots with a waterproof coat should be worn when handling the veterinary medicinal product. Protection 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 eye immediately with water and get medical attention.

In case of accidental injection or spillage onto the skin seek medical advice immediately and show the package leaflet or the label to the physican.

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

Special precautions for the protection of the environment:

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface water or ditches with the product or used containers. Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Other precautions:
Ivermectin is not tolerated well in all non-target species (cases of intolerance with fatal outcome are reported in dogs - especially Collies and Bobtails and also in turtles/tortoises).

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The veterinary medicinal product can be administered to beef cows at any stage of pregnancy or lactation provided that the milk is not intended for human consumption.

3.8 Interaction with other medical products and other forms of interaction

The effects of GABA agonists are increased by ivermectin.

3.9 Administration routes and dosage

Ivermectin should be administered topically at 500 μg per kg bodyweight (1 ml per 10 kg bodyweight).

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

It is recommended that calves which are set-stocked in their first season of grazing should be treated 3, 8 and 13 weeks after turn-out, for optimal benefit from the persistent effect of ivermectin. This can protect the animals from parasitic gastro-enteritis and lungworm disease throughout the grazing season, provided they are set-stocked. All calves should be included in the program, and no untreated cattle should be added to the pasture. Treated animals should be monitored according to good husbandry practices always.

To ensure a correct dosage, body weight should be determined as accurately as possible.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In case of overdose a symptomatic treatment should be given. The symptoms of overdose can be trembling, convulsions and coma.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 28 days.
Not authorised for use in animals producing milk for human consumption.
The product should not be used in non-lactating dairy cows including pregnant heifers within 60 days of calving.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54 AA01

4.2 Pharmacodynamics

Ivermectin is a mixture of two partially modified compounds of abamectin belonging to the avermectin family, which are a macrocyclic lactone group of endoctocides. Abamectin is a mixture of two fermentation products of the soil organism *Streptomyces avermitilis.*

Ivermectin is a macrocyclic lactone derivative and acts by inhibiting nerve impulses. It binds selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the relevant parasites. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA). The margin of safety for compounds of this class is attributable to the fact that mammals do not have glumamate-gated chloride channels. The macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

4.3 Pharmacokinetics

After administration of the recommended dosage to cattle varying inter-individual ivermectin plasma levels were observed with mean values of C_{max} and t_{max} of 11.26 ng/ml and 97 hours, respectively.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 12 months.

5.3 Special precautions for storage

Store below 30°C.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product will be supplied in one 250 ml or 1.0 litre single neck, twin-neck and squeeze-measure high density polyethylene dispensers in a

cardboard box, or one 1 litre high density polyethylene backpacks or 2.5 litre or 5 litre low density polyethylene backpacks in a cardboard box.
Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as Ivermectin is extremely dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6 NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

7 MARKETING AUTHORISATION NUMBER(S)

VPA 22664/056/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 29 October 1999

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

07/06/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.