SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enovex 0.5% w/v Pour-On Solution for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient(s)

Ivermectin	0.5% w/v

Excipient(s)

Patent Blue V (E131)	0.0005% w/v

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Pour-On Solution.
A clear blue pour-on solution.

4. CLINICAL PARTICULARS

4.1 Target species

Beef and non-lactating dairy cattle.

4.2 Indications for use, specifying the target species

Enovex Pour-On is indicated for the effective treatment and control of the following gastrointestinal roundworms, lungworms, eyeworms, warbles, chorioptic and sarcoptic mange and sucking and biting lice in beef and non-lactating dairy cattle.

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), Trichuris spp (adult).

Lungworms (adult and fourth stage larvae):
Dictyocaulus viviparus.

Eyeworms (adult):
Thelazia spp

Warbles (parasitic stages):
Hypoderma bovis, Hypoderma lineatum.

Lice:
Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus, Damalinia bovis.

Mange mites:
Chorioptes bovis, Sarcoptes scabiei var bovis.

Enovex Pour-On 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 viviparis acquired up to 28 days after treatment.

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

4.3 Contraindications

Enovex Pour-on has been formulated for specific use in cattle. It should not be applied or administered to other species, as severe reactions, including fatalities in dogs, may occur.

4.4 Special warnings for each target species

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

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 onocophora in cattle within the EU, in Teladorsagia in cattle in developed countries such as New Zealand and Haemonochus 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.

4.5 Special precautions for use

Cases of intolerance with fatal outcome are reported in dogs, especially Collies, old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises." Do not allow these species to come in contact with this product.
Close container after use.

Special precautions for use in animals

As Ivermectin is extremely dangerous to fish and aquatic life, treated animals should not have direct access to surface water and ditches during treatment.
To avoid secondary reactions due to the death of Hypoderma larvae in the oesophagus or in the spine, it is recommended to administer the product at the end of warble fly activity and before the larvae reach their resting sites.
It is recommended to treat all animals within a herd or group.
The shedding of nematode eggs can continue for some time after treatment.

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

HIGHLY FLAMMABLE, keep away from heat, sparks, open flame or other sources of ignition.

Use only in well ventilated areas or outdoors.
Do not smoke, eat or drink while handling 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 rubber gloves, boots, goggles and a waterproof coat when applying the product. Protective clothing should be washed after use.
As absorption through skin can occur, in the event of accidental skin contact, wash the affected area immediately with soap and water.
If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Undesirable effects are not expected when the product is used at the recommended dose rate.

4.7 Use during pregnancy, lactation or 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

Do not combine ivermectin treatment with vaccination against lungworms. If vaccinated animals are to be treated, treatment should not be carried out within a period of 28 days before or after vaccination.

4.9 Amounts to be administered and administration route

Ivermectin should be administered topically at 500 mg 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.

250 ml bottle and 1 litre pack
(Squeeze dispensing bottle/twin-neck container/single neck container)

- Remove the cap (twin-neck container/single neck container) or attach the dispensing cup to the product bottle (squeeze-measure container) and hold the container in an upright position.
- Gently squeeze the container until the product is level with the desired dose volume increment.
- Dispense the product by tipping the container forward until inverted.

1 litre, 2.5 litre and 5 litre pack
(Collapsible Back Pack)

- Remove the shipping cap from the backpack container and replace with the vent cap provided.
- Attach the hose from the automatic dosing equipment to the outlet from the vent cap.
- Follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and care of the applicator gun following use.

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 signs of toxicity are likely up to 5 mg/kg (10 times the recommended dose rate). There is no known antidote.

4.11 Withdrawal period

Cattle (meat & offal): 28 days
Not to be used on animals producing milk for human consumption. Do not use in non-lactating dairy cows, including pregnant heifers, within 60 days of calving.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Avermectins

ATC vet Code: QP54AA01

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 2 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Patent Blue V (E131)
Crodamol CAP
Triethanolamine
Isopropyl Alcohol

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Do not store above 30 ºC
Protect from light.
Store tightly closed in original container.

6.5 Nature and composition of immediate packaging

250 ml and 1.0 litre natural high density polyethylene twin neck bottle with polypropylene screw cap with woodpulp faced aluminium wad seal.

250 ml and 1.0 litre natural high density polyethylene single neck bottle with polypropylene screw cap with woodpulp faced aluminium wad seal.

250 ml and 1.0 litre natural high density polyethylene squeeze bottle with polypropylene screw cap with woodpulp faced aluminium wad seal.

1 litre white high density polyethylene backpack with polypropylene screw caps with woodpulp faced aluminium wad seal.

2.5 L and 5 litre white low density polyethylene backpack with polypropylene screw caps with woodpulp faced aluminium wad seal.

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

EXTREMELY DANGEROUS to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used containers.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4191

9. DATE OF FIRST AUTHORISATION

19 September 2000

10. DATE OF REVISION OF THE TEXT

March 2023

Approved: 01 March 2023