SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enovex 1.0% w/v Solution for Injection for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient(s)

Ivermectin	1.0% w/v

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection
Clear, colourless to pale yellow sterile non-aqueous solution

4. CLINICAL PARTICULARS

4.1 Target species

Beef and non-lactating dairy cattle.

4.2 Indications for use, specifying the target species

Enovex Injection is indicated for the treatment and control of the following species of gastrointestinal roundworms, lungworms, eyeworms, warbles, mites and sucking lice in beef cattle and non-lactating dairy cattle.

Gastrointestinal roundworms (adults and fourth stage larvae):
Ostertagia ostertagi (including inhibited *O ostertagi*), *Ostertagia lyrata, Haemonchus placei*, *Trichostrongylus axei*, *Trichostrongylus colubriformis*, *Cooperia oncophora, Cooperia punctata, Cooperia pectinata, Bunostomum phlebotomum, Oesophagostomum radiatum, Strongyloides papillosus* (adult), *Nematodirus helvetianus* (adult)*, Nematodirus spathiger* (adult)*,* and *Trichuris* spp (adults)

Lungworms (adult and fourth stage larvae):
Dictyocaulus viviparus

Eyeworms (adult):
Thelazia spp

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

Sucking Lice:
Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus

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

Enovex Injection may also be used as an aid in the control of the biting louse *Damalinia bovis* and the mange mite *Chorioptes bovis*, but complete elimination may not occur.

When cattle have to graze on pasture contaminated with infective larvae of cattle nematodes, treatment with Enovex Injection at the recommended dose rate controls re-infection with *Haemonchus placei, Cooperia* spp and *Trichostrongylus axei* acquired up to 14 days after treatment, *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired up to 21 days after treatment and *Dictyocaulus viviparus* acquired up to 28 days after treatment.

4.3 Contraindications

Enovex Injection is not for intravenous or intramuscular use.

Enovex Injection is a low volume product registered for use in cattle. It should not be used in other species as severe adverse reactions, including fatalities in dogs, may occur.

4.4 Special Warnings for each target species

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* 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 nematode and recommendations on how to limit further selection for resistance to anthelmintics.

4.5 Special precautions for use

(i) Special precautions for use in animals
None

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals
Direct contact of the product with the skin should be kept to a minimum.
Take care to avoid accidental self-administration: this product may cause local irritation and/or pain at the site of injection.
Do not smoke or eat while handling the product.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Transitory discomfort has been observed in some cattle following subcutaneous administration. Tissue swellings at the injection site have been observed. These reactions resolve without treatment.

4.7 Use during pregnancy, lactation or lay

The product can be safely administered to the cow 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

None identified.

4.9 Amounts to be administered and administration route

Ivermectin should be administered at a dosage rate of 200 μg per kg bodyweight (1 ml to 50 kg bodyweight). It should only be injected subcutaneously in front of or behind the shoulder using aseptic technique. A sterile 17 gauge half inch needle is recommended.

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

This product does not contain an antimicrobial preservative. Swab septum before removing each dose. Use a dry sterile needle and syringe. For 250 ml and 500 ml pack sizes, use of a multiple dose syringe is recommended. To refill the syringe, use of a draw-off needle is recommended to avoid excessive broaching of the stopper.
Assess bodyweight as accurately as possible before calculating dosage.

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

Single doses of 4.0 mg/kg ivermectin (20 times the recommended dosage) administered subcutaneously, can result in ataxia and depression. No antidote has been identified. Symptomatic treatment may be beneficial.

4.11 Withdrawal period

Cattle (meat and offal): 49 days
This product should not be used in cattle producing milk for human consumption.
The product should not to be used in non-lactating dairy cows including pregnant heifers, within 60 days of calving.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Avermectins

ATCvet Code: QP54AA01

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

Glycerol Formal
Macrogol 200

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after opening the immediate packaging: 28 days

6.4 Special precautions for storage

Do not store above 30°C.

Protect from light.

Following withdrawal of the first dose use the product within 28 days. Discard unused material. Avoid introduction of contamination.

6.5 Nature and composition of immediate packaging

50 ml, 100 ml, 250 ml, 500 ml and 1 litre high-density polyethylene vials with bromobutyl bungs and aluminium overseals.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials

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

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Newry
Co. Down,
BT35 6JP,
Northern Ireland

8. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4192

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th September 2000

10. DATE OF REVISION OF THE TEXT

December 2009