

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE  
CARTON**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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

**2. STATEMENT OF ACTIVE SUBSTANCES**

**CARTON TEXT FRONT:**

A clear blue pour-on solution containing ivermectin 0.5% w/v (5 mg/ml).

**3. PHARMACEUTICAL FORM**

Pour-On Solution

**4. PACKAGE SIZE**

250 ml / 1 L / 2.5 L / 5 L

**5. TARGET SPECIES**

Beef and non-lactating dairy cattle.

**6. INDICATION(S)**

**CARTON TEXT FRONT:**

For the treatment and control of gastrointestinal nematodes, lungworms, eyeworms, warbles, chorioptic and sarcoptic mange mites and sucking and biting lice of beef and non-lactating dairy cattle.

**CARTON TEXT BACK:**

Enovex Pour-On is for the treatment and control of gastrointestinal nematodes (adult and fourth stage larvae): *Ostertagia ostertagi* including inhibited larvae, *Haemonchus placei*, *Trichostrongylus axei*, *Trichostrongylus colubriformis*, *Cooperia* spp, *Oesophagostomum radiatum*, *Strongyloides papillosus* (adult) and *Trichuris* spp. (adult).

Enovex Pour-On is for the treatment and control of (adult and fourth stage larvae): *Dictyocaulus viviparus*.

Enovex Pour-On is for the treatment and control of eyeworms (adult): *Thelazia* spp.

Enovex Pour-On is for the treatment and control of warbles (parasitic stages): *Hypoderma bovis* and *Hypoderma lineatum*.

Enovex Pour-On is for the treatment and control of mange mites: *Sarcoptes scabiei* var *bovis* and *Chorioptes bovis*.

Enovex Pour-On is for the treatment and control of lice: *Linognathus vituli*, *Haematopinus eurysternus*, *Damalinia bovis* and *Solenopotes capillatus*.

Enovex Pour-On given at the recommended dosage of 500 micrograms ivermectin/ 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 viviparus* acquired up to 28 days after treatment. It also controls horn flies (*Haematobia irritans*) for up to 35 days after treatment.

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

FOR EXTERNAL USE ONLY

**Dosage:** 1 ml per 10 kg bodyweight (based on a recommended dosage level of 500 micrograms ivermectin /kg bodyweight)

**Administration:** The formulation should be applied along the mid-line of the back in a narrow strip between the withers and tailhead.

Example:

Bodyweight (kg)	Dose volume (ml)	Doses per pack
100	10	
150	15	
200	20	
250	25	
300	30	

Over 300 kg bodyweight, give an additional 1 ml for each additional 10 kg bodyweight.

**IMPORTANT: READ PACKAGE INSERT BEFORE USE.**

## 8. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 28 days from the last treatment. Do not use in cows producing milk for human consumption. Do not use in non-lactating dairy cows, including pregnant heifers, within 60 days of calving.

## 9. SPECIAL WARNING(S), IF NECESSARY

Do not treat cattle when their hide or hair 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 may have mange, scabs or other lesions or to areas contaminated with mud or manure.

Enovex Pour-On has been formulated for topical application specifically in cattle. It should not be applied or administered to other species as severe adverse reactions, including fatalities in dogs, may occur.

#### **USER WARNINGS**

**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.

#### **10. EXPIRY DATE**

EXP:

#### **11. SPECIAL STORAGE CONDITIONS**

Do not store above 30°C. Protect from light. Keep container in outer carton. Store in tightly closed original container. Close container when not in use.

If stored at temperatures below 0°C, Enovex Pour-On may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

#### **12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

**EXTREMELY DANGEROUS** to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container.

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

For external use only.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE**

**For animal treatment only.**

POM-VPS

To be supplied only on veterinary prescription

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

**Keep out of the sight and reach of children.**

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Norbrook Laboratories Limited  
Newry, Co. Down  
United Kingdom

**Distributed By:**

Norbrook Laboratories Limited  
Carnbane Industrial Estate  
Newry  
BT35 6QQ, Co Down  
Northern Ireland

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 02000/4191

**17. MANUFACTURER’S BATCH NUMBER**

B.N.:

LOGO

Chemical Group of Anthelmintic Endectocides [3-AV]

FLAME SYMBOL

Highly flammable  
Keep container tightly closed  
Keep away from sources of ignition  
No smoking

**UK AUTHORISED VETERINARY MEDICINAL PRODUCT**



## **PARTICULARS TO APPEAR ON THE LABEL**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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

### **2. STATEMENT OF ACTIVE SUBSTANCES**

A clear blue pour-on solution containing ivermectin 0.5% w/v (5 mg/ml).

### **3. PHARMACEUTICAL FORM**

Pour-On Solution

### **4. PACKAGE SIZE**

250 ml / 1 L / 2.5 L / 5 L

### **5. TARGET SPECIES**

Beef and non-lactating dairy cattle.

### **6. INDICATION(S)**

For the treatment and control of gastrointestinal nematodes, lungworms, eyeworms, warbles, chorioptic and sarcoptic mange and sucking and biting lice of beef and non-lactating dairy cattle.

### **7. METHOD AND ROUTE(S) OF ADMINISTRATION**

1 ml per 10 kg bodyweight (based on a recommended dosage level of 500 micrograms ivermectin per kg bodyweight).

The formulation should be applied topically along the mid-line of the back in a narrow strip between the withers and tailhead.

**IMPORTANT: READ PACKAGE INSERT BEFORE USE.**

### **8. 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

## 9. SPECIAL WARNING(S), IF NECESSARY

Do not treat cattle when their hide or hair 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 may have mange, scabs or other lesions or to areas contaminated with mud or manure.

Enovex Pour-On has been formulated for topical application specifically in cattle. It should not be administered to other species as severe adverse reactions, including fatalities in dogs, may occur.

### USER WARNINGS

**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.

Wash hands after use.

See package leaflet for full user warnings.

## 10. EXPIRY DATE

EXP: dd/mm/yyyy

## 11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Protect from light.

Store in tightly closed original container. Keep container in outer carton.

## 12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

EXTREMELY DANGEROUS to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

**For animal treatment only.**

POM-VPS

To be supplied only on veterinary prescription.

## 14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

**Keep out of the sight and reach of children.**

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Norbrook Laboratories Limited  
Newry, Co. Down  
United Kingdom

**Distributed By:**

Norbrook Laboratories Limited  
Carnbane Industrial Estate  
Newry  
BT35 6QQ, Co Down  
Northern Ireland

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 02000/4191

**17. MANUFACTURER'S BATCH NUMBER**

B.N.:  
DOM:

Chemical Group of Anthelmintic Endectocides [3-AV]

**FOR EXTERNAL USE ONLY**

**UK AUTHORISED VETERINARY MEDICINAL PRODUCT**



LOGO

## PACKAGE LEAFLET FOR:

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

Marketing authorisation holder and manufacturer responsible for batch release:  
Norbrook Laboratories Limited  
Newry, Co. Down  
BT35 6JP  
United Kingdom

### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enovex 0.5% w/v Pour On for Cattle

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

A clear blue Pour-On solution containing ivermectin 0.5% w/v (5 mg/ml).

With this product, Norbrook offers users dosing flexibility in a pour-on, systemically active formulation. Enovex Pour-On contains ivermectin a member of the avermectin class of anthelmintic endectocides.

### 4. INDICATION(S)

For the treatment and control of gastrointestinal nematodes, lungworms, eyeworms, warbles, chorioptic and sarcoptic mange and sucking and biting lice of beef and non-lactating dairy cattle.

Enovex Pour-On applied at the recommended dose rate of 500 micrograms ivermectin per kg is indicated for the control of these parasites:

#### **Gastrointestinal roundworms (adult and fourth stage larvae):**

*Ostertagia ostertagi* (including inhibited larvae), *Haemonchus placei*, *Trichostrongylus axei*, *Trichostrongylus colubriformis*, *Cooperia* spp., *Oesophagostomum radiatum*, *Strongyloides papillosus* (adult), and *Trichuris* spp (adult).

#### **Lungworms (adult and fourth stage larvae):**

*Dictyocaulus viviparus*

#### **Eyeworms (adult):**

*Thelazia* spp

#### **Warbles (parasitic stages):**

*Hypoderma bovis* and *H. lineatum*

**Mange mites:**

*Sarcoptes scabiei* var. *bovis* and *Chorioptes bovis*

**Lice:**

*Linognathus vituli*, *Haematopinus eurysternus*, *Damalinia bovis* and *Solenopotes capillatus*

Enovex Pour-On given at the recommended dosage of 500 micrograms/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; *Dictyocaulus viviparus* acquired up to 28 days after treatment. It also controls horn fly (*Haematobia irritans*) for up to 35 days after treatment.

**5. CONTRAINDICATIONS**

Enovex Pour-On has been formulated for topical application specifically in cattle. It should not be applied or administered to other species as severe adverse reactions, including fatalities in dogs, may occur.

**6. ADVERSE REACTIONS**

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

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

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

**7. TARGET SPECIES**

Beef and non-lactating dairy cattle.

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

1 ml per 10 kg bodyweight (based on a recommended dosage level of 500mcg ivermectin per kg bodyweight).

This product has been formulated only for external application to cattle, do not use in other species.

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

### *Squeeze-Measure-Pour System*

**Important** - Keep upright when filling and during storage.

Close container when not in use and store in an upright position.

## **9. ADVICE ON CORRECT ADMINISTRATION**

The formulation should be applied along the mid-line of the back in a narrow strip between the withers and 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.

## **10. WITHDRAWAL PERIOD(S)**

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 28 days from the last treatment.

Do not use in cows producing milk for human consumption. Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

## **11. SPECIAL STORAGE PRECAUTIONS**

Do not store above 30°C. Protect from light. Keep container in outer carton. Store in tightly closed original container. Close container when not in use.

If stored at temperatures below 0°C, Enovex Pour-On may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

## **12. SPECIAL WARNING(S)**

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.

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 *Haemonchus* 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.

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.

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.

## **USER WARNINGS**

**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.

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

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate ponds, waterways or ditches with the product or used containers.

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

March 2023

**15. OTHER INFORMATION**

**Distributed By:**

Norbrook Laboratories Limited

Carnbane Industrial Estate

Newry

BT35 6QQ, Co Down

Northern Ireland

**PACKAGE INFORMATION**

Enovex Pour-On is available in 250 ml and 1 litre twin-neck packs, single-neck packs or a squeeze-measure-pour system or 1 litre, 2.5 litre and 5 litre collapsible backpack.

Not all pack sizes may be marketed.

**MODE OF ACTION**

Ivermectin paralyses and ultimately kills parasitic nematodes, arachnids, and insects by its effect on the nervous systems of these parasites. Ivermectin belongs to the avermectin class of anthelmintic endectocides. The mode of action exhibited by the avermectins is unique to this class of antiparasitic agents.

Ivermectin belongs to the avermectin [3-AV] class of anthelmintic in the endectocides. Chemical group of anthelmintic endectocides [3-AV].

FLAME SYMBOL Highly flammable  
Keep container tightly closed  
Keep away from sources of ignition  
No smoking

BN:  
D.O.M:  
Exp:

ManA 2000  
Vm 02000/4191

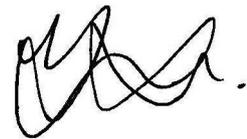
**POM-VPS** To be supplied only on veterinary prescription

**FOR ANIMAL TREATMENT ONLY**

LOGO

**UK AUTHORISED VETERINARY MEDICINAL PRODUCT**

**KEEP OUT OF THE SIGHT AND REACH OF CHILDREN**



Approved: 01 March 2023