Veterinary Medicines Directorate

Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone (01932) 336911 Fax (01932) 336618
Website: www.gov.uk

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enovex 1.0% w/v Solution for Injection for Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Enovex Injection is a ready-to-use 1.0% w/v sterile non-aqueous solution of ivermectin.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml, 100 ml, 250 ml, 500 ml and 1 litre

5. TARGET SPECIES

Beef and non-lactating dairy cattle.

6. INDICATION(S)

CARTON TEXT FRONT:

For the treatment and control* of gastrointestinal roundworms, lungworms, eyeworms, warbles, mites and sucking lice of beef and non-lactating dairy cattle.

*For details see back of carton and package insert.

CARTON TEXT BACK:

Enovex Injection is indicated for the treatment and control of the following species of 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* and *H. lineatum*
Mange mites: *Sarcoptes scabiei* var. *bovis, Psoroptes bovis*
Sucking lice: *Linognathus vituli, Haematopinus eurysternus* and *Solenopotes capillatus*

Enovex Injection controls re-infection with the gastrointestinal worms *Haemonchus placei, Cooperia* spp and *Trichostrongylus axei* acquired up to 14 days after treatment, controls re-infection with gastrointestinal worms *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired up to 21 days after treatment and lungworms (*Dictyocaulus viviparus*) acquired up to 28 days after treatment.

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

Enovex Injection should be given only by subcutaneous injection at the recommended dosage level of 200µg per kg bodyweight (1 ml per 50 kg bodyweight).

For example:

Bodyweight (kg)	Dose Volume (ml)	Doses per Pack
Up to 50	1	
51 - 100	2	
101 - 150	3	
151 - 200	4	
201 - 250	5	
251 - 300	6	

Over 300 kg bodyweight, give an additional 1 ml for each additional 50 kg bodyweight.

This product does not contain an antimicrobial preservative. Swab septum before removing each dose. Use a dry sterile needle and syringe. For 250 ml, 500 ml and 1 litre 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.

8. WITHDRAWAL PERIOD

CARTON TEXT SIDE 1:

Cattle must not be treated within 49 days of slaughter for human consumption.
Do not use in cattle producing milk for human consumption or in non-lactating dairy cows including pregnant heifers within 60 days of calving.

9. SPECIAL WARNING(S), IF NECESSARY

IMPORTANT: READ PACKAGE INSERT BEFORE USE.

The product 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.

Direct contact of the product with the skin should be kept to a minimum
Take care to avoid self-administration: the product may cause irritation and/or pain at the site of injection.
Do not smoke or eat while handling the product. Wash hands after use.

10. EXPIRY DATE

EXP: DD/MM/YY

11. SPECIAL STORAGE CONDITIONS

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

Following withdrawal of the first dose, use the product within 28 days. Discard unused material. Avoid the introduction of contamination. 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 *[Distribution category]*

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 reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder:
Norbrook Laboratories Limited
Newry, Co. Down
Northern Ireland

Distributed by:
Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4192

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

LOGO

CARTON TEXT SIDE 2:

Enovex Injection is a clear colourless sterile solution containing 1.0% w/v ivermectin.

Chemical Group of Anthelmintic Endectocides [3-AV]

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enovex 1.0% w/v Solution for Injection for Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1.0% w/v sterile non-aqueous solution of ivermectin for injection

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 / 100 / 250 / 500 ml / 1 litre

5. TARGET SPECIES

Beef and non-lactating dairy cattle.

6. INDICATION(S)

For the treatment and control* of gastrointestinal roundworms, lungworms, eyeworms, warbles, mites and sucking lice of beef and non-lactating dairy cattle.

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Inject subcutaneously at the rate of 200µg/kg (1 ml per 50 kg bodyweight).

8. WITHDRAWAL PERIOD

Cattle must not be treated within 49 days of slaughter for human consumption. Do not use in cattle producing milk for human consumption or in dairy cows including pregnant heifers within 60 days prior to calving.

9. SPECIAL WARNING(S), IF NECESSARY

This product 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. Assess bodyweight as accurately as possible before calculating dosage.
Direct contact of the product with the skin should be kept to a minimum
Take care to avoid self-administration: the product may cause irritation and/or pain at the site of injection.
Do not smoke or eat while handling the product. Wash hands after use.

10. EXPIRY DATE

EXP: DD/MM/YY

11. SPECIAL STORAGE CONDITIONS

Protect from light. Do not store above 30◦C. This product does not contain any antimicrobial preservative. Swap septum before removing each dose. Use a dry sterile needle and syringe. Avoid introduction of contamination.
Following withdrawal of the first dose, use the product within 28 days. Discard unused material. When using the 250 ml, 500 ml and 1 litre pack sizes, use only multiple dose syringe equipment.
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 *[Distribution category]*

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 reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Manufactured by:

Norbrook Laboratories Limited
Newry
Co. Down,
Northern Ireland

Distributed by:
Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4192

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

Discard by:_____

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

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

PACKAGE LEAFLET FOR:
Enovex 1.0% w/v Solution for Injection for Cattle

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

Norbrook Laboratories Limited
Newry, Co. Down
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enovex 1.0% w/v Solution for Injection for Cattle

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

Enovex Injection is a ready-to-use, sterile, non-aqueous solution of ivermectin. Ivermectin is derived from the avermectins, a family of highly active, broad-spectrum antiparasitic agents which are isolated from fermentation of the soil organism *Streptomyces avermitilis.*

Enovex Injection is a 1.0% w/v sterile solution of ivermectin. At the rate of 1 ml per 50 kg bodyweight by subcutaneous injection, this formulation will deliver the recommended dosage level of 200 μg ivermectin per kg bodyweight.

4. INDICATION(S)

Enovex Injection is indicated for the treatment and control of the following species of gastrointestinal roundworms, lungworms, eyeworms, warbles, mites and sucking lice.

Gastrointestinal roundworms (adult and fourth stage larvae):
Ostertagia ostertagi (including inhibited larval stages), *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 (adult)

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

Eyeworms (adult): *Thelazia* spp

Warbles: *Hypoderma bovis* and *Hypoderma lineatum*

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

Sucking Lice: *Linognathus vituli, Haematopinus eurysternus,* and *Solenopotes capillatus*

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.

Persistent activity
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.

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.

5. CONTRAINDICATIONS

This product is not for intravenous or intramuscular use.
Enovex Injection is a low volume product for cattle: it should not be used in other species as adverse reactions, such as fatalities in dogs, may occur.

6. ADVERSE REACTIONS

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. Further information is available upon request.

If you notice any serious effects or other effects not mentioned in this leaflet, 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

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

Enovex Injection should be given only by subcutaneous injection at the recommended dosage level of 200 μg ivermectin per kilogram bodyweight. Each ml contains 10 mg of ivermectin sufficient to treat 50 kg of bodyweight. Use the following dosage schedule.

Bodyweight (kg)	Dose Volume (ml)
Up to 50	1.0
51 to 100	2.0
101 to 150	3.0
151 to 200	4.0
201 to 250	5.0
251 to 300	6.0
301 to 350	7.0
351 to 400	8.0
401 to 450	9.0
451 to 500	10.0
501 to 550	11.0
551 to 600	12.0

9. ADVICE ON CORRECT ADMINISTRATION

Enovex Injection is to be given subcutaneously only. Assess bodyweight as accurately as possible before calculating dosage. Inject under the loose skin in front of or behind the shoulder. Use of a 17 gauge, half-inch (15-20 mm) needle is suggested. Replace with a fresh sterile needle after every 10-12 animals.

MODE OF ACTION

Ivermectin paralyses and ultimately kills parasitic nematodes, arachnids and insects by its effect on the nervous system of these parasites. At therapeutic doses, ivermectin has no adverse effect on cattle since it does not readily penetrate their central nervous systems. Ivermectin belongs to the avermectin class of anthelmintic endectocides.

10. WITHDRAWAL PERIOD(S)

Cattle must not be treated within 49 days of slaughter for human consumption.
Do not use in cattle 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

This product does not contain any antimicrobial preservative.
Swab septum before removing each dose
Use a dry sterile needle and syringe
When using the 250 ml and 500 ml pack sizes, use only multiple dose syringe equipment. To refill the syringe use of a draw-off needle is recommended to avoid excess broaching of the stopper.
Protect from light. Do not store above 30°C**.**
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material. Avoid introduction of contamination. Keep container in outer carton

12. SPECIAL WARNING(S)

Direct contact of the product with the skin should be kept to a minimum
Take care to avoid self-administration: the product may cause irritation and/or pain at the site of injection.

Do not smoke or eat while handling the product. 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 container. 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

December 2009

15. OTHER INFORMATION

WHEN TO USE ENOVEX INJECTION

The suggested dosing programme has been developed to make the best use of the properties of Enovex Injection. Your veterinary surgeon will be able to provide further advice.

Stomach and Gut Roundworms

Roundworm larvae may survive on the pasture over the winter in great numbers. They infect grazing cattle immediately after turnout, maturing into egg laying worms and causing increased pasture contamination. Early season treatment with Enovex

Injection keeps down the population of worms in your stock and reduces the number of worm eggs passed onto the pasture to cause later infection.

Eyeworms
The presence of these worms may produce irritation and excessive tear formation in the eye. These tears attract flies which are responsible for the transmission of infection to other cattle. The eyeworms are present throughout the year but transmission from one animal to another, and the annoyance caused by the flies, occurs only during the summer months.

Treatment with Enovex Injection controls adult eyeworms in cattle at any time of the year.

Lice and Mites
Autumn treatment with Enovex Injection controls sucking lice, sarcoptic and psoroptic mange mites as infections start to build up. Enovex Injection may also be used as an aid in the control of biting lice and chorioptic mange mites, but complete elimination may not occur. Treat all animals in contact with each other to prevent cross-infection.

Warbles
The best time to treat is in autumn or early winter, when Enovex Injection stops the small migrating larvae before they have time to cause serious damage. Treatment with Enovex Injection kills all stages of warble larvae and may be given whenever convenient for the farmer.

In spring, warbles show as lumps on the backs of previously untreated cattle. Treatment with Enovex Injection kills these larvae, thus further reducing the population of adult flies for next season.

DISTRIBUTED BY:

Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

PACKAGE INFORMATION
Enovex Injection is available in five ready-to-use sizes - 50 ml, 100 ml, 250 ml, 500 ml and 1 litre volumes.

The 50 ml pack is a multiple dose, rubber-capped bottle. Each bottle contains sufficient solution to treat 10 cattle of 250 kg bodyweight.

The 100 ml pack is a multiple dose, rubber-capped bottle. Each bottle contains sufficient solution to treat 20 cattle of 250 kg bodyweight.

The 250 ml pack is a multiple dose, rubber-capped bottle. Each bottle contains sufficient solution to treat 50 cattle of 250 kg bodyweight.

The 500 ml pack is a multiple dose, rubber-capped bottle. Each bottle contains sufficient solution to treat 100 cattle of 250 kg bodyweight.

The 1 litre pack is a multiple dose, rubber-capped bottle. Each bottle contains sufficient solution to treat 200 cattle of 250 kg bodyweight.

Not all pack sizes may be marketed.

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

ManA 2000
Vm 02000/4192

FOR ANIMAL TREATMENT ONLY

POM-VPS

To be supplied only on veterinary prescription

Keep out of the reach and sight of children.

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

LOGO