DRAFT CARTON TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norbonex 5mg/ml Pour-On Solution for Beef and Dairy Cattle
Eprinomectin

2. STATEMENT OF ACTIVE SUBSTANCES

1ml of solution contains:

Active Ingredient:
Eprinomectin: 5 mg

3. PHARMACEUTICAL FORM

Pour-on solution.

4. PACKAGE SIZE

250mL [1L, 2.5L, 5L]

5. TARGET SPECIES

Cattle (beef and dairy cattle)

6. INDICATION(S)

Indicated for treatment and control of infections of the following parasites

Gastrointestinal Roundworms (adults and fourth stage larvae):
Ostertagia spp., *Ostertagia lyrata* (adult), *Ostertagia ostertagi* (including inhibited L_4), *Cooperia* spp. (including inhibited L_4), *Cooperia oncophora, Cooperia pectinata, Cooperia punctata, Cooperia surnabada, Haemonchus placei, Trichostrongylus* spp., *Trichostrongylus axei, Trichostrongylus colubriformis, Bunostomum phlebotomum, Nematodirus helvetianus, Oesophagostomum* spp. (adult), *Oesophagostomum radiatum, Trichuris* spp (adult).

Lungworms (adults and fourth stage larvae):
Dictyocaulus viviparus

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

Mange Mites:

Chorioptes bovis, Sarcoptes scabiei

Lice:
Damalinia (Bovicola) bovis (biting lice), *Linognathus vituli* (sucking lice), *Haematopinus eurysternus* (sucking lice), *Solenopotes capillatus* (sucking lice).

Horn Flies:
Haematobia irritans.

While mite and louse numbers decline rapidly following treatment, due to the feeding habits of the parasites, in some cases several weeks may be required for complete eradication.

Prolonged Activity

Applied as recommended, the product controls reinfections with:

Parasite *	**Prolonged Activity**
Dictyocaulus viviparus	up to 28 days
Ostertagia spp	up to 28 days
Oesophagostomum radiatum	up to 28 days
Cooperia spp	up to 21 days
Trichostrongylus spp	up to 21 days
Haemonchus placei	up to 14 days
Nematodirus helvetianus	up to 14 days

*The following parasite species are included within each of the relevant genera: *Ostertagi ostertagi, O. lyrata, Cooperia oncophora, C. punctata, C. surnabada, Trichostronglus axei, T. colubroformis*.

For best results use as part of a program to control both internal and external parasites of cattle based on the epidemiology of these parasites.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pour-on use.

For single topical application.
To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.
The recommended dose rate is 0.5 mg eprinomectin per kg body weight (equivalent to 1 ml/ 10 kg body weight). The product should be applied topically by pouring along the backline in a narrow strip extending from the withers to the tailhead.

HANDY DOSING GUIDE		ANIMALS SHOULD BE WEIGHED AND GROUPED ACCORDING TO BODYWEIGHT TO AVOID UNDER OR OVER-DOSING*			
BODYWEIGHT	DOSE VOLUME	NUMBER OF FULL DOSES PER PACK			
		250ml	1 litre	2.5 litre	5 litre
100kg	10ml	25	100	250	500
150kg	15ml	16	66	166	333
200kg	20ml	12	50	125	250
250kg	25ml	10	40	100	200
300kg	30ml	8	33	83	166
350kg	35ml	7	28	71	142
400kg	40ml	6	25	62	125
450kg	45ml	5	22	55	111
500kg	50ml	5	20	50	100
550kg	55ml	4	18	45	90
600kg	60ml	4	16	41	83

* Dose rate 1ml per 10kg bodyweight

Rainfall before or after treatment will not affect the efficacy of the product. The influence of extreme weather conditions on long term effect of the product is unknown.

8. WITHDRAWAL PERIOD(S)

Cattle (meat & offal): 10 days
Cattle (milk): zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

Special precautions for use in animals

Do not use in animals with known hypersensitivity to the active ingredient or any of the excipients.

Not to be used in other species; avermectins can cause fatalities in dogs, especially Collies, Old English Sheepdogs and related breeds and crosses, and also in turtles/tortoises.

Eprinomectin is very toxic to aquatic organisms, is persistent in soils and may accumulate in sediments.

Like other macrocyclic lactones, eprinomectin has the potential to adversely affect non-target organisms. Following treatment, excretion of potentially toxic levels of eprinomectin may take place over a period of several weeks. Faeces containing eprinomectin excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms which may impact on the dung degradation.

The risk to aquatic ecosystems and dung fauna can be reduced by avoiding too frequent and repeated use of eprinomectin (and products of the same anthelmintic class) in cattle.

The risk to aquatic ecosystems will be further reduced by keeping treated cattle away from water bodies for two to five weeks after treatment.

For effective use, the product should not be applied to areas of the backline covered with mud or manure. The product should be applied only on healthy skin.

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

Users should wear rubber gloves, boots and a waterproof coat when applying the product.
Inhalation of the product may cause irritation.
Use only in well ventilated areas or outdoors.

Read the package leaflet before use.

10. EXPIRY DATE

EXP: XX-XX-XXXX

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Keep container in the outer carton. Protect from light.
Following withdrawal of the first dose, use the product within 3 months.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Extremely dangerous to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty container.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

FOR ANIMAL TREATMENT ONLY

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

(EU)
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

Distributed by:

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4342

17. MANUFACTURER'S BATCH NUMBER

DRAFT LABEL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norbonex 5mg/ml Pour-On Solution for Beef and Dairy Cattle
Eprinomectin

2. STATEMENT OF ACTIVE SUBSTANCES

1ml of solution contains:

Active Ingredient:
Eprinomectin: 5 mg

3. PHARMACEUTICAL FORM

Pour-on solution.

4. PACKAGE SIZE

250mL [1L, 2.5L, 5L]

5. TARGET SPECIES

Cattle (beef and dairy cattle)

6. INDICATION(S)

For the treatment and control of infections of gastrointestinal roundworms, lungworms warbles, mange mites, lice and horn flies.

For further details please refer to the package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pour-on use.
For single topical application.

Administer only by topical application at the dose rate of 1 ml per 10 kg of body weight, corresponding to the recommended dose rate of 0.5 mg eprinomectin per kg bodyweight.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle (meat & offal): 10 days
Cattle (milk): zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: XX-XX-XXXX

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Keep container in the outer carton. Protect from light.
Following withdrawal of the first dose, use the product within 3 months.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Extremely dangerous to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty container.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

FOR ANIMAL TREATMENT ONLY

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

(EU)
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

Distributed by:

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4342

17. MANUFACTURER'S BATCH NUMBER

DRAFT INSERT TEXT

Norbonex 5mg/ml Pour-On Solution for Beef and Dairy Cattle

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

Marketing Authorisation Holder:
(EU)
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

Manufacturing Authorisation Holder Responsible for Batch Release:
(EU)
Norbrook Manufacturing Ltd
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norbonex 5mg/ml Pour-On Solution for Beef and Dairy Cattle [UK]
Eprizero 5mg/ml Pour-On Solution for Beef and Dairy Cattle [DE]
Eprinomectin

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

1ml of solution contains:

Active Ingredient:
Eprinomectin: 5 mg

Excipients:
Butylated Hydroxytoluene (E321) 0.1mg

A Clear to Very Light Yellow Solution.

4. INDICATION(S)

Indicated for treatment and control of infections of the following parasites

Gastrointestinal Roundworms (adults and fourth stage larvae):
Ostertagia spp., *Ostertagia lyrata* (adult)*, Ostertagia ostertagi* (including inhibited L_4)*, Cooperia* spp. (including inhibited L_4), *Cooperia oncophora, Cooperia pectinata, Cooperia punctata, Cooperia surnabada, Haemonchus placei, Trichostrongylus* spp., *Trichostrongylus axei, Trichostrongylus colubriformis, Bunostomum phlebotomum, Nematodirus helvetianus, Oesophagostomum* spp. (adult), *Oesophagostomum radiatum, Trichuris* spp (adult).
Lungworms (adults and fourth stage larvae):
Dictyocaulus viviparus

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

Mange Mites:
Chorioptes bovis, Sarcoptes scabiei

Lice:
Damalinia (Bovicola) bovis (biting lice), *Linognathus vituli* (sucking lice), *Haematopinus eurysternus* (sucking lice), *Solenopotes capillatus* (sucking lice).

Horn Flies:
Haematobia irritans.

While mite and louse numbers decline rapidly following treatment, due to the feeding habits of the parasites, in some cases several weeks may be required for complete eradication.

Prolonged Activity

Applied as recommended, the product controls reinfections with:

Dictyocaulus viviparus (up to 28 days)
Ostertagia spp (up to 28 days)
*Oesophagostomum radiatum (*up to 28 days)
Cooperia spp (up to 21 days)
Trichostrongylus spp (up to 21 days)
*Haemonchus placei (*up to 14 days)
Nematodirus helvetianus (up to 14 days)

For best results use as part of a program to control both internal and external parasites of cattle based on the epidemiology of these parasites

5. CONTRAINDICATIONS

This product is formulated only for topical application to beef and dairy cattle, including lactating dairy cattle. Do not use in other animal species. Do not administer orally or by injection. Do not use in animals with known hypersensitivity to the active ingredient or any of the excipients.

6. ADVERSE REACTIONS

No undesirable effects have been identified when the product is used at the recommended dose rate.

7. TARGET SPECIES

Cattle (beef and dairy cattle)

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

Pour-on use.
For single topical application.

The recommended dose rate is 0.5 mg Eprinomectin per kg bodyweight (equivalent to 1ml/ 10kg bodyweight) The product should be applied topically by pouring along the backline in a narrow strip extending from the withers to the tailhead.

9. ADVICE ON CORRECT ADMINISTRATION

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

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.

Rainfall before or after treatment will not affect the efficacy of the product. The influence of extreme weather conditions on long term effect of the product is unknown.

10. WITHDRAWAL PERIOD(S)

Cattle (meat & offal): 10 days
Cattle (milk): zero hours.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C. Keep container in the outer carton. Protect from light.
Do not use after the expiry date which is stated on the label.
Following withdrawal of the first dose, use the product within 3 months.
Keep out of the sight and reach of children.

12. SPECIAL WARNINGS

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 bodyweight, 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.

To date no resistance to eprinomectin (a macrocyclic lactone) has been reported within the EU. However resistance to other macrocyclic lactones has been reported in parasite species in cattle within the EU. Therefore, 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.
If there is a risk for re-infection, the advice of a veterinarian should be sought regarding the need for and frequency of repeat administration.

For effective use, the product should not be applied to areas of the backline covered with mud or manure. The product should be applied only on healthy skin.

Not to be used in other species; avermectins can cause fatalities in dogs, especially Collies, Old English Sheepdogs and related breeds and crosses, and also in turtles/tortoises.

In adult cattle, after administration of 5 times the recommended dose (2.5 mg eprinomectin/kg body weight), mild hair loss was observed. No other signs of toxicity were seen.
No antidote has been identified.

Like other macrocyclic lactones, eprinomectin has the potential to adversely affect non-target organisms. Following treatment, excretion of potentially toxic levels of eprinomectin may take place over a period of several weeks. Faeces containing eprinomectin excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms which may impact on the dung degradation.

Eprinomectin is very toxic to aquatic organisms, is persistent in soils and may accumulate in sediments.

The risk to aquatic ecosystems and dung fauna can be reduced by avoiding too frequent and repeated use of eprinomectin (and products of the same anthelmintic class) in cattle.

The risk to aquatic ecosystems will be further reduced by keeping treated cattle away from water bodies for two to five weeks after treatment.

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

This product may be irritating to human skin and eyes and may cause hypersensitivity.
Avoid skin and eye contact with the product during treatment and when handling recently treated animals.
Users should wear rubber gloves, boots and a waterproof coat when applying the product.
Should clothing become contaminated, remove as soon as possible and launder before re-use.
If accidental skin contact occurs, wash the affected area immediately with soap and water.
If accidental eye exposure occurs, flush eyes immediately with water.
This product may be toxic after accidental ingestion.

Avoid accidental ingestion of the product by hand to mouth contact.
Do not smoke, eat or drink while handling the product.
In the event of ingestion, wash out mouth with water and seek medical advice.
Wash hands after use.
This product is flammable. Keep away from sources of ignition.
Inhalation of the product may cause irritation.
Use only in well ventilated areas or outdoors.

Other precautions

Eprinomectin is very toxic to aquatic organisms, is persistent in soils and may accumulate in sediments.

The risk to aquatic ecosystems and dung fauna can be reduced by avoiding too frequent and repeated use of eprinomectin (and products of the same anthelmintic class) in cattle.

The risk to aquatic ecosystems will be further reduced by keeping treated cattle away from water bodies for two to five weeks after treatment.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Extremely dangerous to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty container.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2019

15. OTHER INFORMATION

Package Quantities:
250mL and 1L containers and 1L, 2.5L and 5L backpacks.
Not all package sizes may be marketed

ManA 2000

To be supplied only on veterinary prescription.

Distributed by:

FOR ANIMAL TREATMENT ONLY

Approved: 21 June 2019