

PARTICULARS TO APPEAR ON THE OUTER PACKAGE (250ml CARTON)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eprinex Pour-on for Beef and Dairy Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

0.5% w/v eprinomectin

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

250 ml

5. TARGET SPECIES

Beef and Dairy Cattle

6. INDICATION(S)

For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi* and *Cooperia* spp.), lungworms, warbles, sucking and biting lice, chorioptic and sarcoptic mange mites in beef and dairy cattle.

- EPRINEX Pour-on for Beef and Dairy Cattle may be used in dairy cattle during all stages of pregnancy and lactation
- EPRINEX Pour-on for Beef and Dairy Cattle kills:

Parasite	Adult	L4	Inhibited L4
Gastrointestinal Roundworms:			
<i>Ostertagia</i> spp.	✓	✓	
<i>O. lyrata</i>	✓		
<i>O. ostertagi</i>	✓	✓	✓
<i>Cooperia</i> spp.	✓	✓	✓
<i>C. oncophora</i>	✓	✓	
<i>C. pectinata</i>	✓	✓	
<i>C. punctata</i>	✓	✓	
<i>C. surnabada</i>	✓	✓	
<i>Haemonchus placei</i>	✓	✓	
<i>Trichostrongylus</i> spp.	✓	✓	
<i>T. axei</i>	✓	✓	
<i>T. colubriformis</i>	✓	✓	
<i>Bunostomum phlebotomum</i>	✓	✓	
<i>Nematodirus helvetianus</i>	✓	✓	
<i>Oesophagostomum</i> spp.	✓		
<i>O. radiatum</i>	✓	✓	
<i>Trichuris</i> spp.	✓		
Lungworm:			
<i>Dictyocaulus viviparus</i>	✓	✓	
Warbles (parasitic stages)			
<i>Hypoderma bovis</i>			
<i>H. lineatum</i>			
Mange mites			
<i>Chorioptes bovis</i>			
<i>Sarcoptes scabiei</i> var. <i>bovis</i>			
Lice			
<i>Linognathus vituli</i>			
<i>Haematopinus eurysternus</i>			
<i>Damalinia bovis</i>			
<i>Solenopotes capillatus</i>			

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.

7. DOSAGE AND ADMINISTRATION

Dosage: 1 ml per 10 kg bodyweight (based on a recommended dosage level of 500 mcg eprinomectin/kg bodyweight).

Administration: The formulation should be applied topically by pouring along the backline in a narrow strip extending from the withers to the tailhead.

Bodyweight kg	Dose Volume ml	Doses (per 250ml bottle)
100	10	25
150	15	16
200	20	12
250	25	10
300	30	8

Over 300 kg bodyweight, give 1 ml per 10 kg bodyweight.

8. WITHDRAWAL PERIOD

Milk from cows may be used for human consumption at any time following treatment with EPRINEX Pour-On for Beef and Dairy Cattle. Meat may only be taken for human consumption from 15 days after the last treatment.

9. SPECIAL WARNINGS

IMPORTANT: Read Package Leaflet Before Use

Precautions

Operators should wear rubber gloves when applying the product.

If accidental skin contact occurs, wash the affected area immediately with soap and water.

If accidental eye exposure occurs, flush eyes immediately with water.

Should clothing become contaminated, remove as soon as possible and launder before re-use. In the event of ingestion, wash out mouth with water and seek medical advice.

This product is for topical application to the surface of cattle skin only. Do not administer orally or by injection.

Do not apply to areas of the backline covered with mud or manure.

Do not smoke, eat or drink while handling the product.

Wash hands after use.

EPRINEX Pour-On for Beef and Dairy Cattle is intended for use on cattle only.

Do not use in other species, avermectins can cause fatalities in dogs.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Keep container in the outer carton. Protect from light. Store upright.

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

DANGEROUS TO FISH AND AQUATIC LIFE.

Do not contaminate surface waters 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

To be supplied only on veterinary prescription

POM-VPS

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

Keep out of reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4157

17. MANUFACTURER’S BATCH NUMBER

Batch No.:

18. FURTHER INFORMATION

Prolonged Activity

EPRINEX Pour-On for Beef and Dairy Cattle, applied as recommended, controls reinfections with:

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

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

For best results EPRINEX Pour-On for Beef and Dairy Cattle should be part of a programme to control both internal and external parasites of cattle based on the epidemiology of these parasites.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE (1L CARTON)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eprinex Pour-on for Beef and Dairy Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

0.5% w/v eprinomectin

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

1 litre

5. TARGET SPECIES

Beef and Dairy Cattle

6. INDICATION(S)

For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi* and *Cooperia* spp.), lungworms, warbles, sucking and biting lice, chorioptic and sarcoptic mange mites in beef and dairy cattle.

- EPRINEX Pour-on for Beef and Dairy Cattle may be used in dairy cattle during all stages of pregnancy and lactation
- EPRINEX Pour-on for Beef and Dairy Cattle kills:

Parasite	Adult	L4	Inhibited L4
Gastrointestinal Roundworms:			
<i>Ostertagia</i> spp.	✓	✓	
<i>O. lyrata</i>	✓		
<i>O. ostertagi</i>	✓	✓	✓
<i>Cooperia</i> spp.	✓	✓	✓
<i>C. oncophora</i>	✓	✓	
<i>C. pectinata</i>	✓	✓	
<i>C. punctata</i>	✓	✓	
<i>C. surnabada</i>	✓	✓	
<i>Haemonchus placei</i>	✓	✓	
<i>Trichostrongylus</i> spp.	✓	✓	
<i>T. axei</i>	✓	✓	
<i>T. colubriformis</i>	✓	✓	
<i>Bunostomum phlebotomum</i>	✓	✓	
<i>Nematodirus helvetianus</i>	✓	✓	
<i>Oesophagostomum</i> spp.	✓		
<i>O. radiatum</i>	✓	✓	
<i>Trichuris</i> spp.	✓		
Lungworm:			
<i>Dictyocaulus viviparus</i>	✓	✓	
Warbles (parasitic stages)			
<i>Hypoderma bovis</i>			
<i>H. lineatum</i>			
Mange mites			
<i>Chorioptes bovis</i>			
<i>Sarcoptes scabiei</i> var. <i>bovis</i>			
Lice			
<i>Linognathus vituli</i>			
<i>Haematopinus eurysternus</i>			
<i>Damalinia bovis</i>			
<i>Solenopotes capillatus</i>			

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.

7. DOSAGE AND ADMINISTRATION

Dosage: 1 ml per 10 kg bodyweight (based on a recommended dosage level of 500 mcg eprinomectin/kg bodyweight).

Administration: The formulation should be applied topically by pouring along the backline in a narrow strip extending from the withers to the tailhead.

Bodyweight kg	Dose Volume ml	Doses (per 1 litre bottle)
100	10	100
150	15	66
200	20	50
250	25	40
300	30	33

Over 300 kg bodyweight, give 1 ml per 10 kg bodyweight.

8. WITHDRAWAL PERIOD

Milk from cows may be used for human consumption at any time following treatment with EPRINEX Pour-On for Beef and Dairy Cattle. Meat may only be taken for human consumption from 15 days after the last treatment.

9. SPECIAL WARNINGS

IMPORTANT: Read Package Leaflet Before Use

Precautions

Operators should wear rubber gloves when applying the product.

If accidental skin contact occurs, wash the affected area immediately with soap and water.

If accidental eye exposure occurs, flush eyes immediately with water.

Should clothing become contaminated, remove as soon as possible and launder before re-use. In the event of ingestion, wash out mouth with water and seek medical advice.

This product is for topical application to the surface of cattle skin only. Do not administer orally or by injection.

Do not apply to areas of the backline covered with mud or manure.

Do not smoke, eat or drink while handling the product.

Wash hands after use.

EPRINEX Pour-On for Beef and Dairy Cattle is intended for use on cattle only. Do not use in other species, avermectins can cause fatalities in dogs.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Keep container in the outer carton. Protect from light. Store upright.

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

DANGEROUS TO FISH AND AQUATIC LIFE.

Do not contaminate surface waters 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

To be supplied only on veterinary prescription

POM-VPS

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

Keep out of reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4157

17. MANUFACTURER’S BATCH NUMBER

Batch No.:

18. FURTHER INFORMATION

Prolonged Activity

EPRINEX Pour-On for Beef and Dairy Cattle, applied as recommended, controls reinfections with:

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

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

For best results EPRINEX Pour-On for Beef and Dairy Cattle should be part of a programme to control both internal and external parasites of cattle based on the epidemiology of these parasites.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE (2.5L CARTON)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eprinex Pour-on for Beef and Dairy Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

0.5% w/v eprinomectin

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

2.5 litre

5. TARGET SPECIES

Beef and Dairy Cattle

6. INDICATION(S)

For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi* and *Cooperia* spp.), lungworms, warbles, sucking and biting lice, chorioptic and sarcoptic mange mites in beef and dairy cattle.

- EPRINEX Pour-on for Beef and Dairy Cattle may be used in dairy cattle during all stages of pregnancy and lactation
- EPRINEX Pour-on for Beef and Dairy Cattle kills:

Parasite	Adult	L4	Inhibited L4
Gastrointestinal Roundworms:			
<i>Ostertagia</i> spp.	✓	✓	
<i>O. lyrata</i>	✓		
<i>O. ostertagi</i>	✓	✓	✓
<i>Cooperia</i> spp.	✓	✓	✓
<i>C. oncophora</i>	✓	✓	
<i>C. pectinata</i>	✓	✓	
<i>C. punctata</i>	✓	✓	
<i>C. surnabada</i>	✓	✓	
<i>Haemonchus placei</i>	✓	✓	
<i>Trichostrongylus</i> spp.	✓	✓	
<i>T. axei</i>	✓	✓	
<i>T. colubriformis</i>	✓	✓	
<i>Bunostomum phlebotomum</i>	✓	✓	
<i>Nematodirus helvetianus</i>	✓	✓	
<i>Oesophagostomum</i> spp.	✓		
<i>O. radiatum</i>	✓	✓	
<i>Trichuris</i> spp.	✓		
Lungworm:			
<i>Dictyocaulus viviparus</i>	✓	✓	
Warbles (parasitic stages)			
<i>Hypoderma bovis</i>			
<i>H. lineatum</i>			
Mange mites			
<i>Chorioptes bovis</i>			
<i>Sarcoptes scabiei</i> var. <i>bovis</i>			
Lice			
<i>Linognathus vituli</i>			
<i>Haematopinus eurysternus</i>			
<i>Damalinia bovis</i>			
<i>Solenopotes capillatus</i>			

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.

7. DOSAGE AND ADMINISTRATION

Dosage: 1 ml per 10 kg bodyweight (based on a recommended dosage level of 500 mcg eprinomectin/kg bodyweight).

Administration: The formulation should be applied topically by pouring along the backline in a narrow strip extending from the withers to the tailhead.

Bodyweight kg	Dose Volume ml	Doses (per 2.5 litre bottle)
100	10	250
150	15	166
200	20	125
250	25	100
300	30	83

Over 300 kg bodyweight, give 1 ml per 10 kg bodyweight.

8. WITHDRAWAL PERIOD

Milk from cows may be used for human consumption at any time following treatment with EPRINEX Pour-On for Beef and Dairy Cattle. Meat may only be taken for human consumption from 15 days after the last treatment.

9. SPECIAL WARNINGS

IMPORTANT: Read Package Leaflet Before Use

Precautions

Operators should wear rubber gloves when applying the product.

If accidental skin contact occurs, wash the affected area immediately with soap and water.

If accidental eye exposure occurs, flush eyes immediately with water.

Should clothing become contaminated, remove as soon as possible and launder before re-use. In the event of ingestion, wash out mouth with water and seek medical advice.

This product is for topical application to the surface of cattle skin only. Do not administer orally or by injection.

Do not apply to areas of the backline covered with mud or manure.

Do not smoke, eat or drink while handling the product.

Wash hands after use.

EPRINEX Pour-On for Beef and Dairy Cattle is intended for use on cattle only. Do not use in other species, avermectins can cause fatalities in dogs.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Keep container in the outer carton. Protect from light. Store upright.

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

DANGEROUS TO FISH AND AQUATIC LIFE.

Do not contaminate surface waters 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

To be supplied only on veterinary prescription

POM-VPS

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

Keep out of reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4157

17. MANUFACTURER’S BATCH NUMBER

Batch No.:

18. FURTHER INFORMATION

Prolonged Activity

EPRINEX Pour-On for Beef and Dairy Cattle, applied as recommended, controls reinfections with:

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

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

For best results EPRINEX Pour-On for Beef and Dairy Cattle should be part of a programme to control both internal and external parasites of cattle based on the epidemiology of these parasites.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE (5L CARTON)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eprinex Pour-on for Beef and Dairy Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

0.5% w/v eprinomectin

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

5 litre

5. TARGET SPECIES

Beef and Dairy Cattle

6. INDICATION(S)

For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi* and *Cooperia* spp.), lungworms, warbles, sucking and biting lice, chorioptic and sarcoptic mange mites in beef and dairy cattle.

- EPRINEX Pour-on for Beef and Dairy Cattle may be used in dairy cattle during all stages of pregnancy and lactation
- EPRINEX Pour-on for Beef and Dairy Cattle kills:

Parasite	Adult	L4	Inhibited L4
Gastrointestinal Roundworms:			
<i>Ostertagia</i> spp.	✓	✓	
<i>O. lyrata</i>	✓		
<i>O. ostertagi</i>	✓	✓	✓
<i>Cooperia</i> spp.	✓	✓	✓
<i>C. oncophora</i>	✓	✓	
<i>C. pectinata</i>	✓	✓	
<i>C. punctata</i>	✓	✓	
<i>C. surnabada</i>	✓	✓	
<i>Haemonchus placei</i>	✓	✓	
<i>Trichostrongylus</i> spp.	✓	✓	
<i>T. axei</i>	✓	✓	
<i>T. colubriformis</i>	✓	✓	
<i>Bunostomum phlebotomum</i>	✓	✓	
<i>Nematodirus helvetianus</i>	✓	✓	
<i>Oesophagostomum</i> spp.	✓		
<i>O. radiatum</i>	✓	✓	
<i>Trichuris</i> spp.	✓		
Lungworm:			
<i>Dictyocaulus viviparus</i>	✓	✓	
Warbles (parasitic stages)			
<i>Hypoderma bovis</i>			
<i>H. lineatum</i>			
Mange mites			
<i>Chorioptes bovis</i>			
<i>Sarcoptes scabiei</i> var. <i>bovis</i>			
Lice			
<i>Linognathus vituli</i>			
<i>Haematopinus eurysternus</i>			
<i>Damalinia bovis</i>			
<i>Solenopotes capillatus</i>			

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.

7. DOSAGE AND ADMINISTRATION

Dosage: 1 ml per 10 kg bodyweight (based on a recommended dosage level of 500 mcg eprinomectin/kg bodyweight).

Administration: The formulation should be applied topically by pouring along the backline in a narrow strip extending from the withers to the tailhead.

Bodyweight kg	Dose Volume ml	Doses (per 5 litre bottle)
100	10	500
150	15	333
200	20	250
250	25	200
300	30	166

Over 300 kg bodyweight, give 1 ml per 10 kg bodyweight.

8. WITHDRAWAL PERIOD

Milk from cows may be used for human consumption at any time following treatment with EPRINEX Pour-On for Beef and Dairy Cattle. Meat may only be taken for human consumption from 15 days after the last treatment.

9. SPECIAL WARNINGS

IMPORTANT: Read Package Leaflet Before Use

Precautions

Operators should wear rubber gloves when applying the product.

If accidental skin contact occurs, wash the affected area immediately with soap and water.

If accidental eye exposure occurs, flush eyes immediately with water.

Should clothing become contaminated, remove as soon as possible and launder before re-use. In the event of ingestion, wash out mouth with water and seek medical advice.

This product is for topical application to the surface of cattle skin only. Do not administer orally or by injection.

Do not apply to areas of the backline covered with mud or manure.

Do not smoke, eat or drink while handling the product.

Wash hands after use.

EPRINEX Pour-On for Beef and Dairy Cattle is intended for use on cattle only. Do not use in other species, avermectins can cause fatalities in dogs.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Keep container in the outer carton. Protect from light. Store upright.

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

DANGEROUS TO FISH AND AQUATIC LIFE.

Do not contaminate surface waters 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

To be supplied only on veterinary prescription

POM-VPS

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

Keep out of reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4157

17. MANUFACTURER’S BATCH NUMBER

Batch No.:

18. FURTHER INFORMATION

Prolonged Activity

EPRINEX Pour-On for Beef and Dairy Cattle, applied as recommended, controls reinfections with:

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

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

For best results EPRINEX Pour-On for Beef and Dairy Cattle should be part of a programme to control both internal and external parasites of cattle based on the epidemiology of these parasites.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS (250 ml, 1 litre, 2.5 litre and 5 litre BOTTLE - FRONT LABEL)**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eprinex Pour-on for Beef and Dairy Cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

0.5% w/v eprinomectin

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

250 ml

1 litre

2.5 litre

5 litre

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

Milk from cows may be used for human consumption at any time following treatment with EPRINEX Pour-On for Beef and Dairy Cattle. Meat withdrawal: 15 days.

6. BATCH NUMBER

7. EXPIRY DATE

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

9. FURTHER INFORMATION

For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi* and *Cooperia* spp.), lungworms, warbles, sucking and biting lice, chorioptic and sarcoptic mange mites in beef and dairy cattle.

IMPORTANT: Read Package Leaflet Before Use

Boehringer Ingelheim

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (250 ml, 1 litre, 2.5 litre, 5 litre BOTTLE - BACK LABEL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eprinex Pour-on for Beef and Dairy Cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE

0.5% w/v eprinomectin

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4. ROUTE OF ADMINISTRATION

Dosage: 1 ml per 10 kg bodyweight (based on a recommended dosage level of 500 mcg eprinomectin/kg bodyweight).

Administration: The formulation should be applied topically by pouring along the backline in a narrow strip extending from the withers to the tailhead

5. WITHDRAWAL PERIOD

Milk from cows may be used for human consumption at any time following treatment with EPRINEX Pour-On for Beef and Dairy Cattle. Meat may only be taken for human consumption from 15 days after the last treatment.

6. BATCH NUMBER

Batch No:

7. EXPIRY DATE

Expiry Date:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

9. FURTHER INFORMATION

Prolonged Activity

EPRINEX Pour-On for Beef and Dairy Cattle, applied as recommended, controls reinfections with:

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

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

For best results EPRINEX Pour-On for Beef and Dairy Cattle should be part of a programme to control both internal and external parasites of cattle based on the epidemiology of these parasites.

Precautions

Operators should wear rubber gloves when applying the product. If accidental skin contact occurs, wash the affected area immediately with soap and water.

If accidental eye exposure occurs, flush eyes immediately with water.

Should clothing become contaminated, remove as soon as possible and launder before re-use. In the event of ingestion, wash out mouth with water and seek medical advice.

This product is for topical application to the surface of cattle skin only. Do not administer orally or by injection. Do not apply to areas of the backline covered with mud or manure. Do not smoke, eat or drink while handling the product. Wash hands after use.

EPRINEX Pour-On for Beef and Dairy Cattle is intended for use on cattle only. Do not use in other species, avermectins can cause fatalities in dogs.

Keep out of reach of children.

DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters 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.

Keep container in the outer carton. Protect from light. Store upright.

Marketing authorization number:
Vm 08327/4157

POM-VPS

To be supplied only on veterinary prescription.

Marketing Authorisation Holder:

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

PACKAGE LEAFLET FOR: Eprinex Pour-on 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:

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Manufacturer responsible for batch release:

Boehringer Ingelheim Animal Health France SCS
4 Chemin du Calquet – 31000 TOULOUSE
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eprinex Pour-on for Beef and Dairy Cattle

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

5 mg/ml eprinomectin

4. INDICATION(S)

For treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi* and *Cooperia* spp.), lungworms, warbles, sucking and biting lice, chorioptic and sarcoptic mange mites in beef and dairy cattle.

EPRINEX Pour-On for Beef and Dairy Cattle, applied at the recommended dose volume of 1 ml/10 kg bodyweight, to achieve a dose level of 500 mcg eprinomectin/kg, is indicated for treatment and control of the following parasites:

Parasite	Adult	L4	Inhibited L4
Gastrointestinal Roundworms:			
<i>Ostertagia</i> spp.	✓	✓	
<i>O. lyrata</i>	✓		
<i>O. ostertagi</i>	✓	✓	✓
<i>Cooperia</i> spp.	✓	✓	✓
<i>C. oncophora</i>	✓	✓	
<i>C. pectinata</i>	✓	✓	
<i>C. punctata</i>	✓	✓	
<i>C. surnabada</i>	✓	✓	
<i>Haemonchus placei</i>	✓	✓	
<i>Trichostrongylus</i> spp.	✓	✓	
<i>T. axei</i>	✓	✓	
<i>T. colubriformis</i>	✓	✓	
<i>Bunostomum phlebotomum</i>	✓	✓	
<i>Nematodirus helvetianus</i>	✓	✓	
<i>Oesophagostomum</i> spp.	✓		
<i>O. radiatum</i>	✓	✓	
<i>Trichuris</i> spp.	✓		
Lungworm:			
<i>Dictyocaulus viviparus</i>	✓	✓	
Warbles (parasitic stages)			
<i>Hypoderma bovis</i>			
<i>H. lineatum</i>			
Mange mites			
<i>Chorioptes bovis</i>			
<i>Sarcoptes scabiei</i> var. <i>bovis</i>			
Lice			
<i>Linognathus vituli</i>			
<i>Haematopinus eurysternus</i>			
<i>Damalinia bovis</i>			
<i>Solenopotes capillatus</i>			

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.

5. CONTRAINDICATIONS

This product is for topical application only. Do not administer orally or by injection.

6. ADVERSE REACTIONS

EPRINEX Pour-On for Beef and Dairy Cattle is intended for use on cattle only. Do not use in other species, avermectins can cause fatalities in dogs. Do not use in animals with known hypersensitivity to the active ingredient or any of the excipients.

7. TARGET SPECIES

Beef and Dairy Cattle

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

Dosage

The product is formulated for external application only to beef and dairy cattle, including lactating dairy cattle. The product should be applied topically by pouring along the backline in a narrow strip extending from the withers to the tailhead. The dose is 1 ml for each 10 kg bodyweight. To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

9. ADVICE ON CORRECT ADMINISTRATION

Dosing cup with Measure-Squeeze-Pour System (250 ml and 1 litre bottles)

The 250 ml pack contains one 25 ml dosing cup and one dip tube. The 1 litre pack contains one 60 ml dosing cup and one dip tube.

- Insert the dip tube into base of the dosing cup. Leave the “slotted end” of the dip tube exposed in the bottom of the bottle.
- Unscrew the bottle cap from the top of the bottle. Screw the dosing cup onto the top of the bottle.
- Measure: To select the correct dose rate, rotate the adjuster cap at the top of the cup in either direction to position the dose indicator to the weight of the animal you want to treat. When body weight is between markings, use the higher setting.
- Squeeze the bottle gently to fill the dosing cup to the required dose. Release your grip and any excess will return to the bottle.
- Pour: Apply the full dose by tipping and pouring along the backline of the animal until the dosing cup is empty.
- The dosing cup should not remain attached to the bottle when not in use. Detach the dosing cup after each use and replace the bottle cap.

Back-pack (2.5 and 5 litre)

Connect the dosing gun and draw-off tubing to the back-pack as follows:

- Attach the open end of the draw-off tubing to an appropriate dosing gun.
- Attach draw-off tubing to the cap with the stem that is included in the pack. Replace shipping cap with the cap having the draw-off tubing. Tighten the draw-off cap.
- Gently prime the dosing gun, checking for leaks.
- Follow the dosing gun manufacturer's directions for adjusting the dose and proper use and maintenance of the dosing gun and draw-off tubing.

10. WITHDRAWAL PERIOD(S)

Meat may only be taken for human consumption from 15 days after the last treatment. There is no milk withdrawal period for lactating cattle. Milk from treated cows may be used for human consumption at any time following treatment with EPRINEX Pour-On for Beef and Dairy Cattle.

11. SPECIAL STORAGE PRECAUTIONS

Keep the container in the outer carton.
Protect from light. Store upright.

The dosing cup should not be stored attached to the bottle when not in use. Remove the cup after each use and replace with the bottle cap.

12. SPECIAL WARNINGS

Cows and heifers may be treated with EPRINEX Pour-On for Beef and Dairy Cattle at any stage of pregnancy. Studies have demonstrated a wide safety margin. Studies conducted at three times the recommended use level of 0.5 mg eprinomectin per kg bodyweight had no adverse effect on breeding performance of cows or bulls.

Do not apply to areas of the backline covered with mud or manure.

Operators should wear rubber gloves when applying the product.

If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with copious water.

Do not smoke, eat or drink while handling the product.
Wash hands after use.

Should clothing become contaminated, remove as soon as possible and launder before re-use. In the event of ingestion, wash out mouth with water and seek medical advice.

For Animal Treatment Only.

Keep out of the sight and reach of children.

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

DANGEROUS TO FISH AND AQUATIC LIFE.

Do not contaminate surface waters 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

15. OTHER INFORMATION

Introduction

EPRINEX Pour-On for Beef and Dairy Cattle provides control of internal and external parasites in one low-volume application. EPRINEX Pour-On for Beef and Dairy Cattle contains eprinomectin, a unique chemical entity. Its convenience, broadspectrum efficacy, wide margin of safety and zero milk withdrawal period make it an ideal product for parasite control in beef and dairy cattle, including lactating dairy cows.

Prolonged Activity

EPRINEX Pour-On for Beef and Dairy Cattle, applied as recommended, controls reinfections with:

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

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

For best results EPRINEX Pour-On for Beef and Dairy Cattle should be part of a programme to control both internal and external parasites of cattle based on the epidemiology of these parasites.

Mode of Action

Eprinomectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve or muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA). The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels; the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels, and they do not readily cross the blood-brain barrier.

Note to User

Rainfall before or after treatment will not affect the efficacy of the product.

Contra-indications, Warnings, etc.

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.

Package Information

EPRINEX Pour-On for Beef and Dairy Cattle is available in four pack sizes—250 ml, 1 litre, 2.5 litre and 5 litre.

The 250 ml bottle is provided with a 25 ml dosing cup.
Each bottle contains sufficient solution to treat 10 x 250 kg cattle.

The 1 litre bottle is provided with a 60 ml dosing cup.
Each bottle contains sufficient solution to treat 40 x 250 kg cattle.

The 2.5 litre pack is a back-pack designed for use with a suitable automatic dispensing gun. Each pack contains sufficient solution to treat 100 x 250 kg cattle.

The 5 litre pack is a back-pack designed for use with a suitable automatic dispensing gun. Each pack contains sufficient solution to treat 200 x 250 kg cattle.

Not all pack sizes may be marketed.

POM-VPS

To be supplied only on veterinary prescription.

Marketing authorisation number:

Vm 08327/4157

Approved 27 May 2020

A handwritten signature in black ink, appearing to read "Hunter.", is positioned below the approval date.