PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARTON

250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dectomax 5 mg/ml Pour-On Solution for Cattle (UK)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Doramectin 5mg/ml

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

250 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For treatment of gastrointestinal roundworms, lungworms, eyeworms, warbles, sucking and biting lice, mange mites and hornfly in cattle.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

1 ml (5 mg doramectin) per 10 kg body weight administered by the topical route on the back of the animal. Dosing guidelines are provided in the following table:

Weight (kg)	**Dose (ml)**
Up to 50 kg	5 ml*
51 – 100 kg	10 ml
101 – 150 kg	15 ml
151 – 200 kg	20 ml
201 – 250 kg	25 ml
251 – 300 kg	30 ml
301 – 350 kg	35 ml
351 – 400 kg	40 ml
401 – 450 kg	45 ml
451 – 500 kg	50 ml

(*When administering the dose with a recommended dosing-gun)
For animals heavier than 500 kg, increase the dose by 5 ml for each additional 1 – 50 kg body weight.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 35 days.

Not permitted for use in lactating animals producing milk for human consumption.
Do not use in pregnant cows or heifers, which are intended to produce milk for human consumption, within 2 months of expected parturition.

9. SPECIAL WARNING(S), IF NECESSARY

Doramectin is very toxic to dung fauna and aquatic organisms and may accumulate in sediments.

Like other macrocyclic lactones, doramectin has the potential to adversely affect non-target organisms. Following treatment, excretion of potentially toxic levels of doramectin may take place over a period of several weeks. Faeces containing doramectin 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 doramectin (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.

The product has been formulated for topical application specifically for cattle. It should not be administered to other species as severe adverse reactions, including fatalities in dog may occur.
This product should be applied to skin surface only. Do not administer orally or parenterally.
Operators should wear rubber gloves and boots with a waterproof coat when applying the product. If accidental skin contact occurs, 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.
HIGHLY FLAMMABLE – Keep away from heat, sparks, open flame or other source of ignition.
For full information regarding anthelmintic resistance, contraindications, operator precautions, disposal advice and special warnings, please read the package leaflet.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store at temperatures below 30 °C.
Do not refrigerate.
Protect from light.
Keep the container in the outer carton.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

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

For animal treatment only.

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

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 00879/4201

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARTON

1 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dectomax 5 mg/ml Pour-On Solution for Cattle (UK)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Doramectin 5mg/ml

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

1 L

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For treatment of gastrointestinal roundworms, lungworms, eyeworms, warbles, sucking and biting lice, mange mites and hornfly in cattle.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

1 ml (5 mg doramectin) per 10 kg body weight administered by the topical route on the back of the animal. Dosing guidelines are provided in the following table:

Weight (kg)	**Dose (ml)**
Up to 50 kg	5 ml*
51 – 100 kg	10 ml
101 – 150 kg	15 ml
151 – 200 kg	20 ml
201 – 250 kg	25 ml
251 – 300 kg	30 ml
301 – 350 kg	35 ml
351 – 400 kg	40 ml
401 – 450 kg	45 ml
451 – 500 kg	50 ml

(*When administering the dose with a recommended dosing-gun)
For animals heavier than 500 kg, increase the dose by 5 ml for each additional 1 – 50 kg body weight.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 35 days.

Not permitted for use in lactating animals producing milk for human consumption.
Do not use in pregnant cows or heifers, which are intended to produce milk for human consumption, within 2 months of expected parturition.

9. SPECIAL WARNING(S), IF NECESSARY

Doramectin is very toxic to dung fauna and aquatic organisms and may accumulate in sediments.

Like other macrocyclic lactones, doramectin has the potential to adversely affect non-target organisms. Following treatment, excretion of potentially toxic levels of doramectin may take place over a period of several weeks. Faeces containing doramectin 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 doramectin (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.

The product has been formulated for topical application specifically for cattle. It should not be administered to other species as severe adverse reactions, including fatalities in dog may occur.
This product should be applied to skin surface only. Do not administer orally or parenterally.
Operators should wear rubber gloves and boots with a waterproof coat when applying the product. If accidental skin contact occurs, 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.
HIGHLY FLAMMABLE – Keep away from heat, sparks, open flame or other source of ignition.
For full information regarding anthelmintic resistance, contraindications, operator precautions, disposal advice and special warnings, please read the package leaflet.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store at temperatures below 30 °C.
Do not refrigerate.
Protect from light.
Keep the container in the outer carton.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

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

For animal treatment only.

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

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4201

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARTON

2.5 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dectomax 5 mg/ml Pour-On Solution for Cattle (UK)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Doramectin 5mg/ml

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

2.5 L

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For treatment of gastrointestinal roundworms, lungworms, eyeworms, warbles, sucking and biting lice, mange mites and hornfly in cattle.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

1 ml (5 mg doramectin) per 10 kg body weight administered by the topical route on the back of the animal. Dosing guidelines are provided in the following table:

Weight (kg)	**Dose (ml)**
Up to 50 kg	5 ml*
51 – 100 kg	10 ml
101 – 150 kg	15 ml
151 – 200 kg	20 ml
201 – 250 kg	25 ml
251 – 300 kg	30 ml
301 – 350 kg	35 ml
351 – 400 kg	40 ml
401 – 450 kg	45 ml
451 – 500 kg	50 ml

(*When administering the dose with a recommended dosing-gun)
For animals heavier than 500 kg, increase the dose by 5 ml for each additional 1 – 50 kg body weight.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 35 days.

Not permitted for use in lactating animals producing milk for human consumption.
Do not use in pregnant cows or heifers, which are intended to produce milk for human consumption, within 2 months of expected parturition.

9. SPECIAL WARNING(S), IF NECESSARY

Doramectin is very toxic to dung fauna and aquatic organisms and may accumulate in sediments.

Like other macrocyclic lactones, doramectin has the potential to adversely affect non-target organisms. Following treatment, excretion of potentially toxic levels of doramectin may take place over a period of several weeks. Faeces containing doramectin 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 doramectin (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.

The product has been formulated for topical application specifically for cattle. It should not be administered to other species as severe adverse reactions, including fatalities in dog, may occur.
This product should be applied to skin surface only.
Do not administer orally or parenterally.
Do not apply to areas of skin which are contaminated with mud or manure.
In rare cases small necrotic small necrotic skin lesions may occur at the administration site.
Avermectins may not be well tolerated in all non-target species. Cases of intolerance with fatal outcome are reported in dogs, especially Collies, old English Sheepdogs and related breeds or crosses, and also in turtles/tortoise. Care should be taken to avoid ingestion of spilled product or access to containers by these other species.
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:
- too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- under dosing, which may be due to underestimation of bodyweight, misadministration of the product, or lack of calibration of a 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 a different pharmacological class and having a different mode of action should be used.
Therapeutic efficacy for internal and external parasites is not affected by heavy rainfall (2 cm in 1 hour) either before (20 minutes) or after (20 and 40 minutes) treatment. The influence of extreme weather conditions on efficacy is unknown.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.
If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- and over-dosing.
Dectomax Pour-On for cattle may be irritating to human skin and eyes and users should be carefully not to apply it to themselves or to other persons. Operators should wear rubber gloves and boots with a waterproof coat when applying the product. Protective clothing should be washed after use. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.
Do not smoke or eat while handling the product.
Wash hands after use.
HIGHLY FLAMMABLE – Keep away from heat, sparks, open flame or other source of ignition.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store at temperatures below 30 °C.
Do not refrigerate.
Protect from light.
Keep the container in the outer carton.

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

Extremely dangerous for fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container.
Any unused product or waste materials should be disposed of in accordance with national requirements.

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

For animal treatment only.

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

Elanco Europe Ltd.

Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4201

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARTON

3 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dectomax 5 mg/ml Pour-On Solution for Cattle (UK)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Doramectin 5mg/ml

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

3 L

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For treatment of gastrointestinal roundworms, lungworms, eyeworms, warbles, sucking and biting lice, mange mites and hornfly in cattle.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

1 ml (5 mg doramectin) per 10 kg body weight administered by the topical route on the back of the animal. Dosing guidelines are provided in the following table:

Weight (kg)	**Dose (ml)**
Up to 50 kg	5 ml*
51 – 100 kg	10 ml
101 – 150 kg	15 ml
151 – 200 kg	20 ml
201 – 250 kg	25 ml
251 – 300 kg	30 ml
301 – 350 kg	35 ml
351 – 400 kg	40 ml
401 – 450 kg	45 ml
451 – 500 kg	50 ml

(*When administering the dose with a recommended dosing-gun)
For animals heavier than 500 kg, increase the dose by 5 ml for each additional 1 – 50 kg body weight.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 35 days.

Not permitted for use in lactating animals producing milk for human consumption.
Do not use in pregnant cows or heifers, which are intended to produce milk for human consumption, within 2 months of expected parturition.

9. SPECIAL WARNING(S), IF NECESSARY

Doramectin is very toxic to dung fauna and aquatic organisms and may accumulate in sediments.

Like other macrocyclic lactones, doramectin has the potential to adversely affect non-target organisms. Following treatment, excretion of potentially toxic levels of doramectin may take place over a period of several weeks. Faeces containing doramectin 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 doramectin (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.

The product has been formulated for topical application specifically for cattle. It should not be administered to other species as severe adverse reactions, including fatalities in dog, may occur.
This product should be applied to skin surface only.
Do not administer orally or parenterally.
Do not apply to areas of skin which are contaminated with mud or manure.
In rare cases small necrotic small necrotic skin lesions may occur at the administration site.
Avermectins may not be well tolerated in all non-target species. Cases of intolerance with fatal outcome are reported in dogs, especially Collies, old English Sheepdogs and related breeds or crosses, and also in turtles/tortoise. Care should be taken to avoid ingestion of spilled product or access to containers by these other species.
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:
- too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- under dosing, which may be due to underestimation of bodyweight, misadministration of the product, or lack of calibration of a 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 a different pharmacological class and having a different mode of action should be used.
Therapeutic efficacy for internal and external parasites is not affected by heavy rainfall (2 cm in 1 hour) either before (20 minutes) or after (20 and 40 minutes) treatment. The influence of extreme weather conditions on efficacy is unknown.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.
If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- and over-dosing.
Dectomax Pour-On for cattle may be irritating to human skin and eyes and users should be carefully not to apply it to themselves or to other persons. Operators should wear rubber gloves and boots with a waterproof coat when applying the product. Protective clothing should be washed after use. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.
Do not smoke or eat while handling the product.
Wash hands after use.
HIGHLY FLAMMABLE – Keep away from heat, sparks, open flame or other source of ignition.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store at temperatures below 30 °C.
Do not refrigerate.
Protect from light.
Keep the container in the outer carton.

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

Extremely dangerous for fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container.
Any unused product or waste materials should be disposed of in accordance with national requirements.

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

For animal treatment only.

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

Elanco Europe Ltd.

Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4201

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARTON

5 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dectomax 5 mg/ml Pour-On Solution for Cattle (UK)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Doramectin 5mg/ml

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

5 L

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For treatment of gastrointestinal roundworms, lungworms, eyeworms, warbles, sucking and biting lice, mange mites and hornfly in cattle.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

1 ml (5 mg doramectin) per 10 kg body weight administered by the topical route on the back of the animal. Dosing guidelines are provided in the following table:

Weight (kg)	**Dose (ml)**
Up to 50 kg	5 ml*
51 – 100 kg	10 ml
101 – 150 kg	15 ml
151 – 200 kg	20 ml
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251 – 300 kg	30 ml
301 – 350 kg	35 ml
351 – 400 kg	40 ml
401 – 450 kg	45 ml
451 – 500 kg	50 ml

(*When administering the dose with a recommended dosing-gun)
For animals heavier than 500 kg, increase the dose by 5 ml for each additional 1 – 50 kg body weight.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 35 days.

Not permitted for use in lactating animals producing milk for human consumption.
Do not use in pregnant cows or heifers, which are intended to produce milk for human consumption, within 2 months of expected parturition.

9. SPECIAL WARNING(S), IF NECESSARY

Doramectin is very toxic to dung fauna and aquatic organisms and may accumulate in sediments.

Like other macrocyclic lactones, doramectin has the potential to adversely affect non-target organisms. Following treatment, excretion of potentially toxic levels of doramectin may take place over a period of several weeks. Faeces containing doramectin 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 doramectin (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.

The product has been formulated for topical application specifically for cattle. It should not be administered to other species as severe adverse reactions, including fatalities in dog, may occur.
This product should be applied to skin surface only.
Do not administer orally or parenterally.
Do not apply to areas of skin which are contaminated with mud or manure.
In rare cases small necrotic small necrotic skin lesions may occur at the administration site.
Avermectins may not be well tolerated in all non-target species. Cases of intolerance with fatal outcome are reported in dogs, especially Collies, old English Sheepdogs and related breeds or crosses, and also in turtles/tortoise. Care should be taken to avoid ingestion of spilled product or access to containers by these other species.
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:
- too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- under dosing, which may be due to underestimation of bodyweight, misadministration of the product, or lack of calibration of a 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 a different pharmacological class and having a different mode of action should be used.
Therapeutic efficacy for internal and external parasites is not affected by heavy rainfall (2 cm in 1 hour) either before (20 minutes) or after (20 and 40 minutes) treatment. The influence of extreme weather conditions on efficacy is unknown.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.
If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- and over-dosing.
Dectomax Pour-On for cattle may be irritating to human skin and eyes and users should be carefully not to apply it to themselves or to other persons. Operators should wear rubber gloves and boots with a waterproof coat when applying the product. Protective clothing should be washed after use. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.
Do not smoke or eat while handling the product.
Wash hands after use.
HIGHLY FLAMMABLE – Keep away from heat, sparks, open flame or other source of ignition.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store at temperatures below 30 °C.
Do not refrigerate.
Protect from light.
Keep the container in the outer carton.

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

Extremely dangerous for fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container.
Any unused product or waste materials should be disposed of in accordance with national requirements.

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

For animal treatment only.

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

Elanco Europe Ltd.

Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4201

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BOTTLE - 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dectomax 5 mg/ml Pour-On Solution for Cattle (UK)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Doramectin 5 mg/ml

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

250 ml

4. ROUTE(S) OF ADMINISTRATION

Pour-on use.

5. WITHDRAWAL PERIOD

Meat and offal: 35 days.

Not permitted for use in lactating animals producing milk for human consumption.
Do not use in pregnant cows or heifers, which are intended to produce milk for human consumption, within 2 months of expected parturition.

6. SPECIAL WARNING(S), IF NECESSARY

Doramectin is very toxic to dung fauna and aquatic organisms and may accumulate in sediments.

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The product has been formulated for topical application specifically for cattle. It should not be administered to other species as severe adverse reactions, including fatalities in dog may occur.
This product should be applied to skin surface only. Do not administer orally or parenterally.
Operators should wear rubber gloves and boots with a waterproof coat when applying the product. If accidental skin contact occurs, 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.
HIGHLY FLAMMABLE – Keep away from heat, sparks, open flame or other source of ignition.
For full information regarding anthelmintic resistance, contraindications, operator precautions, disposal advice and special warnings, please read the package leaflet.

7. BATCH NUMBER

Lot {number}

8. EXPIRY DATE

EXP {month/year}

9. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

10. THE WORDS "KEEP THE CONTAINER IN THE OUTER CARTON"

Keep the container in the outer carton.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BOTTLE - 1 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dectomax 5 mg/ml Pour-On Solution for Cattle (UK)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Doramectin 5 mg/ml

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

1 L

4. ROUTE(S) OF ADMINISTRATION

Pour-on use.

5. WITHDRAWAL PERIOD

Meat and offal: 35 days.

Not permitted for use in lactating animals producing milk for human consumption.
Do not use in pregnant cows or heifers, which are intended to produce milk for human consumption, within 2 months of expected parturition.

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Operators should wear rubber gloves and boots with a waterproof coat when applying the product. If accidental skin contact occurs, 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.
HIGHLY FLAMMABLE – Keep away from heat, sparks, open flame or other source of ignition.
For full information regarding anthelmintic resistance, contraindications, operator precautions, disposal advice and special warnings, please read the package leaflet.

7. BATCH NUMBER

Lot {number}

8. EXPIRY DATE

EXP {month/year}

9. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

10. THE WORDS "KEEP THE CONTAINER IN THE OUTER CARTON"

Keep the container in the outer carton.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BOTTLE - 2.5 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dectomax 5 mg/ml Pour-On Solution for Cattle (UK)
Dectomax 5 mg/ml Pour-on solution pour bovins (BE)
Dectomax Pour on (DE, LU)
Zearl Pour on (FR)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Doramectin 5 mg/ml

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

2.5 L

4. ROUTE(S) OF ADMINISTRATION

Pour-on use.

5. WITHDRAWAL PERIOD

Meat and offal: 35 days.

Not permitted for use in lactating animals producing milk for human consumption.
Do not use in pregnant cows or heifers, which are intended to produce milk for human consumption, within 2 months of expected parturition.

6. SPECIAL WARNING(S), IF NECESSARY

Doramectin is very toxic to dung fauna and aquatic organisms and may accumulate in sediments.

Like other macrocyclic lactones, doramectin has the potential to adversely affect non-target organisms. Following treatment, excretion of potentially toxic levels of doramectin may take place over a period of several weeks. Faeces containing doramectin 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 doramectin (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.

The product has been formulated for topical application specifically for cattle. It should not be administered to other species as severe adverse reactions, including fatalities in dog, may occur.
This product should be applied to skin surface only.
Do not administer orally or parenterally.
Do not apply to areas of skin which are contaminated with mud or manure.
In rare cases small necrotic small necrotic skin lesions may occur at the administration site.

Avermectins may not be well tolerated in all non-target species. Cases of intolerance with fatal outcome are reported in dogs, especially Collies, old English Sheepdogs and related breeds or crosses, and also in turtles/tortoise. Care should be taken to avoid ingestion of spilled product or access to containers by these other species.
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:
- too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- under dosing, which may be due to underestimation of bodyweight, misadministration of the product, or lack of calibration of a 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 a different pharmacological class and having a different mode of action should be used.
Therapeutic efficacy for internal and external parasites is not affected by heavy rainfall (2 cm in 1 hour) either before (20 minutes) or after (20 and 40 minutes) treatment. The influence of extreme weather conditions on efficacy is unknown.
To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.
If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- and over-dosing.
Dectomax Pour-On for cattle may be irritating to human skin and eyes and users should be carefully not to apply it to themselves or to other persons. Operators should wear rubber gloves and boots with a waterproof coat when applying the product. Protective clothing should be washed after use. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.
Do not smoke or eat while handling the product.
Wash hands after use.
HIGHLY FLAMMABLE – Keep away from heat, sparks, open flame or other source of ignition.

7. BATCH NUMBER

Lot {number}

8. EXPIRY DATE

EXP {month/year}

9. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

10. THE WORDS “KEEP THE CONTAINER IN THE OUTER CARTON”

Keep the container in the outer carton.

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

Extremely dangerous for fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container.
Any unused product or waste materials should be disposed of in accordance with national requirements.

MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BOTTLE - 3 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dectomax 5 mg/ml Pour-On Solution for Cattle (UK)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Doramectin 5 mg/ml

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

3 L

4. ROUTE(S) OF ADMINISTRATION

Pour-on use.

5. WITHDRAWAL PERIOD

Meat and offal: 35 days.

Not permitted for use in lactating animals producing milk for human consumption.
Do not use in pregnant cows or heifers, which are intended to produce milk for human consumption, within 2 months of expected parturition.

6. SPECIAL WARNING(S), IF NECESSARY

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The risk to aquatic ecosystems and dung fauna can be reduced by avoiding too frequent and repeated use of doramectin (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.
The product has been formulated for topical application specifically for cattle. It should not be administered to other species as severe adverse reactions, including fatalities in dog, may occur.
This product should be applied to skin surface only.
Do not administer orally or parenterally.
Do not apply to areas of skin which are contaminated with mud or manure.

In rare cases small necrotic small necrotic skin lesions may occur at the administration site Avermectins may not be well tolerated in all non-target species. Cases of intolerance with fatal outcome are reported in dogs, especially Collies, old English Sheepdogs and related breeds or crosses, and also in turtles/tortoise. Care should be taken to avoid ingestion of spilled product or access to containers by these other species.
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:
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Dectomax Pour-On for cattle may be irritating to human skin and eyes and users should be carefully not to apply it to themselves or to other persons. Operators should wear rubber gloves and boots with a waterproof coat when applying the product. Protective clothing should be washed after use. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.
Do not smoke or eat while handling the product.
Wash hands after use.
HIGHLY FLAMMABLE – Keep away from heat, sparks, open flame or other source of ignition.

7. BATCH NUMBER

Lot {number}

8. EXPIRY DATE

EXP {month/year}

9. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

10. THE WORDS “KEEP THE CONTAINER IN THE OUTER CARTON”

Keep the container in the outer carton.

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

Extremely dangerous for fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container.
Any unused product or waste materials should be disposed of in accordance with national requirements.

MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING UNITS

BOTTLE - 5 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dectomax 5 mg/ml Pour-On Solution for Cattle (UK)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Doramectin 5 mg/ml

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

5 L

4. ROUTE(S) OF ADMINISTRATION

Pour-on use.

5. WITHDRAWAL PERIOD

Meat and offal: 35 days.

Not permitted for use in lactating animals producing milk for human consumption.
Do not use in pregnant cows or heifers, which are intended to produce milk for human consumption, within 2 months of expected parturition.

6. SPECIAL WARNING(S), IF NECESSARY

Doramectin is very toxic to dung fauna and aquatic organisms and may accumulate in sediments.

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The risk to aquatic ecosystems and dung fauna can be reduced by avoiding too frequent and repeated use of doramectin (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.

The product has been formulated for topical application specifically for cattle. It should not be administered to other species as severe adverse reactions, including fatalities in dog, may occur.
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Do not apply to areas of skin which are contaminated with mud or manure.

In rare cases small necrotic small necrotic skin lesions may occur at the administration site.
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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.
- under dosing, which may be due to underestimation of bodyweight, misadministration of the product, or lack of calibration of a 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 a different pharmacological class and having a different mode of action should be used.
Therapeutic efficacy for internal and external parasites is not affected by heavy rainfall (2 cm in 1 hour) either before (20 minutes) or after (20 and 40 minutes) treatment. The influence of extreme weather conditions on efficacy is unknown.
To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- and over-dosing.
Dectomax Pour-On for cattle may be irritating to human skin and eyes and users should be carefully not to apply it to themselves or to other persons. Operators should wear rubber gloves and boots with a waterproof coat when applying the product. Protective clothing should be washed after use. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.
Do not smoke or eat while handling the product.
Wash hands after use.
HIGHLY FLAMMABLE – Keep away from heat, sparks, open flame or other source of ignition.

7. BATCH NUMBER

Lot {number}

8. EXPIRY DATE

EXP {month/year}

9. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

10. THE WORDS “KEEP THE CONTAINER IN THE OUTER CARTON”

Keep the container in the outer carton.

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

Extremely dangerous for fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container.
Any unused product or waste materials should be disposed of in accordance with national requirements.

PACKAGE LEAFLET

Dectomax 5 mg/ml Pour-On Solution for 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:
Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

Manufacturer responsible for batch release:
Norbrook Laboratories Limited
Station Works
Newry BT35 6JP
Northern Ireland
United Kingdom

Elanco France S.A.S.
26 rue de 1a Chapelle
68330 Huningue
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dectomax 5 mg/ml Pour-On Solution for Cattle (UK)

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

1 ml Dectomax 5 mg/ml Pour-On Solution contains the following:

Active substance<s>:	Doramectin	5 mg
Excipient(s):	Cetearyl octanoate	160.00 mg
	Triethanolamine	0.5 mg
	Isopropanol	to 1 ml

4. INDICATION(S)

For treatment of gastrointestinal roundworms, lungworms, eyeworms, warbles, sucking and biting lice, mange mites and hornfly in cattle.

Gastrointestinal roundworms (adults and fourth stage larvae)
Ostertagia ostertagi (inc. inhibited larvae)
O. lyrata[1]
Haemonchus placei

Trichostrongylus axei
T. colubriformis
Cooperia oncophora
C. punctata[1]
C. surnabada[1] *(syn. mcmasteri)*
Bunostomum phlebotomum[1]
Oesophagostomum radiatum
Trichuris spp[1]

[1] adults

Lungworms (adults and fourth stage larvae)
Dictyocaulus viviparus
Eyeworms (adults)
Thelazia spp

Warbles (parasitic stages)
Hypoderma bovis, H. lineatum
Biting lice
Damalinia (Bovicola) bovis
Sucking lice
Haematopinus eurystemus,
Linognathus vituli,
Solenopotes capillatus
Mange mites
Psoroptes bovis,
Sarcoptes scabiei,
Chorioptes bovis
Horn fly
Haematobia irritans

Duration of activity

Dectomax Pour-On protects cattle against infection or re-infection with the following parasites for the periods indicated.

Species	Days
Ostertagia ostertagi	35
Cooperia oncophora	28
Dictyocaulus viviparus	42
Linognathis vituli	49
Oesophagostomum radiatum	21
Damalinia (Bovicola) bovis	42
Trichostrongylus axei	28
Solenopotes capillatus	35

Dectomax Pour-On also controls horn flies (*Haematobia irritans*) for at least 42 days after treatment.

To obtain optimal benefit from Dectomax Pour-On for cattle, it is recommended that cattle which are set-stocked should be treated at turn-out and eight weeks later. Used

in this way Dectomax Pour-On for cattle will reduce the build-up of infective larvae on pasture and protect such animals from parasitic gastroenteritis and parasitic bronchitis throughout the grazing season. To obtain these results, all animals should be included in the programme and untreated cattle must not be introduced to the pasture. However due to unpredictable nature of lungworm epidemiology, clinical signs of lungworm disease may on occasion be seen, particularly towards the end of the grazing season, if the season is long. If this occurs, cattle should be further treated against lungworms.

5. CONTRAINDICATIONS

The product has been formulated for topical application specifically for cattle. It should not be administered to other species as severe adverse reactions, including fatalities in dogs, may occur.
Do not use in lactating cows used to produce milk for human consumption, or in dry cows or pregnant dairy heifers within 60 days prior to calving.
Do not use in cases of hypersensitivity to the active substance or any of the excipients.

6. ADVERSE REACTIONS

In rare cases small skin lesions may occur at the administration site.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle.

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

Administer Dectomax Pour-On for cattle topically at a dosage of 500 µg of doramectin per kilogram body weight i.e. 1 ml of solution/10 kg body weight.
The product should be applied topically along the mid-line of the back in a narrow strip between the withers and 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.
If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- and over-dosing.

Directions for using the dosing cup (250 ml and 1 litre bottles only):
A. Rotate the cup on the bottle neck until tight (so the spout is aligned at the mid point on the wide side of the bottle). When the dosing cup is in the closed position ("zero" at set dosage mark on the screw), product does not enter the cup reservoir.

B. Select the dose (1 ml per 10 kg body weight):
- twist the dosing screw to the desired position, so that the correct number of ml is shown at the set dose mark.
- the first complete turn of the dosing screw will set the dose at 10 ml (i.e. 100 kg body weight): "10" shows on the screw at set dose mark. Each additional turn increases the dose in 5 ml increments (i.e. 50 kg body weight) up to 50 ml. When body weight is between weight markings on the dosing cup, use the higher dose volume.

C. Overfill the dosing cup by squeezing the bottle, until the level of liquid goes over the selected dose, then release the pressure. The liquid will automatically come down to the selected dose.

D. Pour the product along the back of the animal.

Directions for using a pour-on applicator* (2.5 litre, 3 litre and 5 litre backpack):
Connect the pour-on applicator to the backpack as follows:
Attach the open end of the draw-off tubing to the pour-on applicator.
Thread the draw off tubing through the antikink spring.
Attach draw-off tubing to the cap with the stem, then screw the spring counter-clockwise over the tubing and draw off stem. Replace shipping cap with the cap that has the draw-off tubing. Tighten the draw-off cap. Invert the backpack.
Gently prime the pour-on applicator, checking for leaks.
Follow manufacturer's directions for correct use and care of equipment.
*Applicators compatible with this formulation are available for use with Dectomax Pour-On for cattle. Other applicators may be incompatible with this formulation.

10. WITHDRAWAL PERIOD

Meat and offal: 35 days.

Not permitted for use in lactating animals producing milk for human consumption.
Do not use in pregnant cows or heifers, which are intended to produce milk for human consumption, within 2 months of expected parturition.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the container in the outer carton.
Do not store above 30^{o}C. Do not refrigerate. Protect from light.
Do not use after the expiry date which is stated on the label and carton.
If stored at temperatures below 4º C Dectomax Pour-On for cattle may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

12. SPECIAL WARNING(S)

For animal treatment only.

Doramectin is very toxic to dung fauna and aquatic organisms and may accumulate in sediments.

Like other macrocyclic lactones, doramectin has the potential to adversely affect non-target organisms. Following treatment, excretion of potentially toxic levels of doramectin may take place over a period of several weeks. Faeces containing doramectin 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 doramectin (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.

This product should be applied to skin surface only. Do not apply to areas of skin which are contaminated with mud or manure.
Do not administer orally or parenterally.
Avermectins may not be well tolerated in all non-target species. Cases of intolerance with fatal outcome are reported in dogs, especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles/tortoise. Care should be taken to avoid ingestion of spilled product or access to containers by these other species.
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:
- too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- under dosing, which may be due to underestimation of bodyweight, misadministration of the product, or lack of calibration of a 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 a different pharmacological class and having a different mode of action should be used.
To avoid secondary reactions due to death of *Hypoderma* larvae in the oesophagus or the spine, it is recommended to administer Dectomax Pour-on at the end of the period of warble fly activity and before the larvae reach their resting sites. Consult your veterinary surgeon on the correct timing of treatment.
Therapeutic efficacy for internal and external parasites is not affected by heavy rainfall (2 cm in 1 hour) either before (20 minutes) or after (20 and 40 minutes) treatment. The influence of extreme weather conditions on efficacy is unknown.
Dectomax Pour-On for cattle may be irritating to human skin and eyes and users should be careful not to apply it to themselves or to other persons. Operators should wear rubber gloves and boots with a waterproof coat when applying the product. Protective clothing should be washed after use. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.
Do not smoke or eat while handling the product. Wash hands after use.
HIGHLY FLAMMABLE – Keep away from heat, sparks, open flame or other sources of ignition.

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

Extremely dangerous for fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container.
Any unused product or waste materials should be disposed of in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2020

15. OTHER INFORMATION

Dectomax Pour-On for cattle is a ready-to-use, colourless, solution containing 0.5% w/v doramectin (5mg/ml). It is formulated to deliver the recommended dosage of 500 µg/kg body weight when given by topical administration at the rate of 1 ml/10 kg body weight.

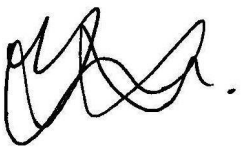
Dectomax Pour-On for cattle is a highly active broad spectrum parasiticide for topical administration to cattle. It contains doramectin, a novel fermentation-derived compound discovered by Pfizer. Doramectin is isolated from fermentation of selected strains derived from the soil organism *Streptomyces avermitilis.*

A primary mode mode of action of doramectin is to modulate chloride ion channel activity in the nervous system of nematodes and arthropods. Doramectin binds to receptors that increase membrane permeability to chloride ions. This inhibits the electrical activity of nerve cells in nematodes and muscle cells in arthropods and causes paralysis and death of the parasites. In mammals the neuronal receptors to which doramectin binds are localised within the central nervous system (CNS), a site reached by only negligible concentrations of doramectin.

Broad-spectrum: a single treatment with Dectomax Pour-On for cattle effectively treats and controls a wide range of internal parasites (roundworms) and external parasites (arthropods) that impair the health and productivity of cattle.

Safety: Dectomax Pour-On for cattle has a wide margin of safety in all classes of cattle.

Dectomax Pour-On for cattle is available in 250 ml, 1 litre, 2.5 litre, 3 litre, and 5 litre multi-dose dispensers. Not all pack sizes may be marketed.



Approved: 23 December 2020