PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE -

VIAL - 200 ml, 250 ml or 500ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dectomax 10 mg/ml Solution for Injection for Cattle & Sheep
Doramectin

2. STATEMENT OF ACTIVE SUBSTANCES

Doramectin 10.00 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

200 ml
250 ml
500 ml

5. TARGET SPECIES

Cattle and sheep.

6. INDICATION(S)

Cattle:
Dosage 1 ml/50 kg by subcutaneous injection. For the treatment and control of gastrointestinal roundworms, lungworms, eye-worms, warbles, lice and mange mites in cattle.

Sheep:
For the treatment and control of *Psoroptes ovis* (sheep scab mite) and *Nematodirus battus*, a dosage of 1 ml/33 kg bodyweight should be used by intramuscular injection. For the treatment of gastrointestinal roundworms and nasal bots in sheep a dosage of 1 ml/50 kg by intramuscular injection.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Cattle and Sheep: Meat and offal: 70 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.
Do not use in pregnant ewes, which are intended to produce milk for human consumption, within 70 days of expected parturition.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

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

10. EXPIRY DATE

EXP {month/year}
Once broached, use by ___/___

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Protect from direct sunlight – do not remove from the protective plastic overwrap.

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

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 the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Kernfarm B.V., De Corridor 14D, 3621 ZB Breukelen, The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 43877/4011

17. MANUFACTURER'S BATCH NUMBER

Lot

Adverse events should be reported to the MAPI holder.
To report an adverse event, ring +44 7543 556682

Manufactured by Zoetis Belgium SA
Procured from within the EU and repackaged by the licence holder:
Kernfarm B.V., De Corridor 14D, 3621 ZB Breukelen, The Netherlands

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

PLASTIC CONTAINER OR CARTON BOX – 200 ml, 250 ml, 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dectomax 10 mg/ml Solution for Injection for Cattle & Sheep
Doramectin

2. STATEMENT OF ACTIVE SUBSTANCES

Doramectin 10.00 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

200 ml
250 ml
500 ml

5. TARGET SPECIES

Cattle and sheep.

6. INDICATION(S)

Cattle:
Dosage 1 ml/50 kg by subcutaneous injection. For the treatment and control of gastrointestinal roundworms, lungworms, eye-worms, warbles, lice and mange mites in cattle.

Sheep:
For the treatment and control of *Psoroptes ovis* (sheep scab mite) and *Nematodirus battus*, a dosage of 1 ml/33 kg bodyweight should be used by intramuscular injection. For the treatment of gastro-intestinal roundworms and nasal bots in sheep a dosage of 1 ml/50 kg by intramuscular injection.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

This product does not contain an antimicrobial preservative.
Swab the septum before removing each dose. Use a dry, sterile needle and syringe.

8. WITHDRAWAL PERIOD(S)

Cattle and Sheep: Meat and offal: 70 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.
Do not use in pregnant ewes, which are intended to produce milk for human consumption, within 70 days 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 and sheep.
The risk to aquatic ecosystems will be further reduced by keeping treated cattle away from water bodies for two to five weeks after treatment.

Read the package leaflet before use.

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

10. EXPIRY DATE

Date of first product withdrawal:
Date when product should be discarded:

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Protect from direct sunlight – do not remove from the protective plastic overwrap.
Following withdrawal of the first dose, use the product within 28 Days.

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

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 the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Kernfarm B.V., De Corridor 14D, 3621 ZB Breukelen, The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 43877/4011

17. MANUFACTURER'S BATCH NUMBER

Lot

Adverse events should be reported to the MAPI holder.
To report an adverse event, ring +44 7543 556682

Manufactured by Zoetis Belgium SA
Procured from within the EU and repackaged by the licence holder:
Kernfarm B.V., De Corridor 14D, 3621 ZB Breukelen, The Netherlands

PACKAGE LEAFLET:
Dectomax 10 mg/ml Solution for Injection for Cattle and Sheep

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

Marketing Authorisation Holder:
Kernfarm B.V.
De Corridor 14D
3621 ZB Breukelen
The Netherlands

Manufacturer for batch release:
Zoetis Belgium SA
Rue Laid Burniat 1
B-1348 Louvain La Neuve
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dectomax 10 mg/ml Solution for Injection for Cattle and Sheep
Doramectin

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

PRESENTATION:
DECTOMAX solution for injection is a ready-to-use, colourless to pale yellow, sterile solution containing 1% w/v doramectin (10 mg/ml).

4. INDICATION(S)

USES:
DECTOMAX solution for injection is a highly active broad spectrum endectocide for parenteral administration to cattle and sheep. It contains doramectin, a novel fermentation-derived avermectin discovered by Pfizer.

Cattle:
DECTOMAX solution for injection is indicated for the treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, eye-worms, warbles, lice and mange mites in cattle.

Gastrointestinal roundworms (adults and fourth stage larvae):
Ostertagia ostertagi (including inhibited larvae)
*O. lyrata**
Haemonchus placei
Trichostrongylus axei
T. colubriformis
Cooperia oncophora
*C. pectinata**

C. punctata
C. surnabada (syn. mcmasteri)
*Nematodirus spathiger**
*Bunostomum phlebotomum**
*Strongyloides papillosus**
Oesophagostomum radiatum
Trichuris spp.*
* adults

Lungworms: (adults and fourth stage larvae)
Dictyocaulus viviparus

Eyeworms: (adults)
Thelazia spp.

Warbles: (parasitic stages)
Hypoderma bovis
H. lineatum

Sucking lice:
Haematopinus eurysternus
Linognathus vituli
Solenopotes capillatus

Mange mites:
Psoroptes bovis
Sarcoptes scabiei

DECTOMAX solution for injection may also be used as an aid in the control of *Nematodirus helvetianus,* of biting lice (*Damalinia bovis*) and the mange mite *Chorioptes bovis.*

The pharmacokinetics of DECTOMAX solution for injection allow protection of cattle against infection or re-infection with *Ostertagia ostertagi* for up to 35 days, *Cooperia oncophora* up to 21 days, *Dictyocaulus viviparus* up to 35 days, *Bunostomum phlebotomum* up to 22 days, *Oesophagostomum radiatum* up to 21 days, *Trichostrongylus axei* up to 28 days, *Linognathus vituli* up to 28 days and *Psoroptes bovis* 42 days.

To obtain optimal benefits from the action of DECTOMAX solution for injection, it is recommended that cattle which are set-stocked should be treated at turnout and eight weeks later. Studies have demonstrated that, used in this way, DECTOMAX will reduce the build-up of infective larvae on pasture and can protect animals from parasitic gastro-enteritis and parasitic bronchitis throughout the grazing season.

To obtain these results, all animals must be included in the programme and untreated cattle must not be introduced on the pasture. Treated cattle should always be monitored according to good husbandry practices. Treatment with DECTOMAX solution for injection at turn-out and eight weeks later of cattle set-stocked for the grazing season can protect against clinical disease caused by lungworm and may allow the development of naturally acquired immunity.

However, due to the 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 with an anthelmintic effective against lungworm.

Sheep:
DECTOMAX solution for injection, is indicated for treatment and control of *Psoroptes ovis* (sheep scab mite) and *Nematodirus battus* at the recommended dose rate of 300 mcg/kg bodyweight (1 ml/33 kg).

DECTOMAX solution for injection is indicated for the following species of gastrointestinal roundworms and nasal bots in sheep at the recommended dose rate of 200 mcg per kilogram bodyweight (1 ml/50 kg):

Gastrointestinal roundworms (Adults and fourth stage larvae (L4) unless otherwise indicated):
Chabertia ovina (adults only)
Cooperia curticei (L4 only)
C. oncophora
Gaigeria pachycelis
Haemonchus contortus
Nematodirus battus (L4 only)[1]
Ostertagia (Teladorsagia) circumcincta [*]
Oesophagostomum columbianum
Strongyloides papillosus
Trichostrongylus axei
T. colubriformis
T. vitrinus
Trichuris spp (Adults only)

[*] Inhibited larval stages (L_4) including strains that are benzimidazole resistant, are also controlled.

[1] For effective treatment and control of both adults and L4 larvae of *Nematodirus battus* a dose rate of 300 mcg/kg is required.

Nasal bots (1st, 2nd and 3rd instar larvae)
Oestrus ovis

5. CONTRAINDICATIONS

Can be used in pregnant non-dairy ewes.
Assess bodyweight as accurately as possible before calculating dosage.
Administer the calculated dose accurately, particularly when treating young lambs.
DECTOMAX solution for injection should not be used in dogs, as severe reactions may occur. In common with other avermectins, certain breeds of dogs, such as collies, are especially sensitive to doramectin and particular care should be taken to avoid accidental consumption of the product.

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device (if any).

Suspected clinical cases of resistance to anthelrnintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used. Resistance to doramectin (an avermectin) has been reported in *Teladorsagia* and *Haemonchus* in sheep within the EU. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

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

6. ADVERSE REACTIONS

None known.

7. TARGET SPECIES

Cattle and sheep.

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

Cattle
Administer DECTOMAX solution for injection at a dosage of 200 mcg doramectin per kilogram of bodyweight by the subcutaneous route.
Each ml contains 10 mg of doramectin, sufficient to treat 50 kg of bodyweight. Each injection should be made into the neck region using a dry sterile 16 to 18 gauge needle, 15 mm in length.

Sheep
For the treatment and control of *Psoroptes ovis* (sheep scab mite) and *Nematodirus battus*, a dosage of 300 mcg/kg bodyweight should be used by the intramuscular route. Each ml contains 10 mg of doramectin, sufficient to treat 33 kg of bodyweight.

In adult sheep each intramuscular injection should be made using a dry sterile 16 to 18 gauge needle, 25 mm in length. (For the treatment of individual sheep a 2 ml disposable syringe calibrated in increments of 0.1 ml should be used).
Suggested dose rates for *Psoroptes ovis* (sheep scab mite) and *Nematodirus battus* 1 ml/33 kg bodyweight (300 mcg/kg).

Sheep over 16 kg bodyweight:

Bodyweight	Dose
17 – 25 kg	0.75 ml
26 – 33 kg	1.0 ml
34 – 41 kg	1.25 ml
42 – 50 kg	1.5 ml
51 – 58 kg	1.75 ml
59 – 66 kg	2.0 ml
67 – 74 kg	2.25 ml
75 – 83 kg	2.5 ml
84 – 91 kg	2.75 ml
92 – 99 kg	3.0 ml

In young lambs of less than 16 kg bodyweight seek veterinary advice regarding the use of appropriate sized needles and of 1 ml disposable syringes graduated in increments of 0.1 ml or less.

Suggested dose rates at 1 ml/33 g bodyweight (300 mcg/kg) in young lambs:

Bodyweight	Dose
Less than 4 kg	0.1 ml
5 – 6 kg	0.2 ml
7 – 10 kg	0.3 ml
11 – 13 kg	0.4 ml
14 – 16 kg	0.5 ml

For the treatment of gastro-intestinal roundworms and nasal bots, administer DECTOMAX solution for injection once at a dosage of 200 mcg doramectin per kilogram of bodyweight by the intramuscular route. Each ml contains 10 mg of doramectin, sufficient to treat 50 kg of bodyweight.

9. ADVICE ON CORRECT ADMINISTRATION

Dectomax is a clear, sterile solution. In common with other non-aqueous formulations the product contains no antimicrobial preservative. Dry, sterile equipment and aseptic procedures should therefore be used when administering Dectomax to animals. Swab the septum before removing the dose. When the temperature of the formulation is below 5°C, syringeability may be improved by gently warming the injecting equipment and product.
When treating groups of animals, use only the Dectomax automatic dosing device and vented draw-off apparatus. When treating individual animals syringes must be filled from the vial through a dry, sterile draw-off needle that has been placed in the vial stopper. Vial stoppers must not be broached more than one time.

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

10. WITHDRAWAL PERIOD(s)

Animals must not be slaughtered for human consumption during treatment.

Cattle:
Meat and offal: 70 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.

Sheep:
Meat and offal: 70 days
Not permitted for use in lactating animals producing milk for human consumption.
Do not use in pregnant ewes, which are intended to produce milk for human consumption, within 70 days of expected parturition.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C. Protect from direct sunlight – do not remove from the protective plastic overwrap.
Following withdrawal of the first dose, use the product within 28 days.

Any product remaining after this period should be discarded.
The discard date should be worked out and written in the space provided on the container label.

12. SPECIAL WARNING(S)

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

Operator warnings
Do not eat, drink or smoke while handling the product.
Wash hands after use. Take care to avoid accidental self - injection - seek medical attention should any specific signs be noticed.
Advice to Medical Doctors: in cases of accidental self-injection specific symptoms have rarely been observed and therefore any cases should be treated symptomatically.

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

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

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

October 2023

15. OTHER INFORMATION

Package quantities: Multi-dose vial of 200 ml, 250 ml and 500 ml. Not all pack sizes may be marketed.

Further information:
Sheep scab (caused by *Psoroptes ovis*) is an extremely contagious disease. In view of sheep scab control requirements in the UK, treatment with 300 mcg doramectin per kg bodyweight is recommended to ensure elimination of all mites. In addition, where possible, adequate bio-security measures should be implemented to prevent re-infestation.

Ensure that all sheep which have been in contact with infested sheep are treated. After treatment, contact between treated infected and untreated uninfected flocks must be avoided for at least 14 days.

When used for scab treatment in sheep, DECTOMAX solution for injection is also effective against certain gastro-intestinal roundworms, and this treatment may form part of a worm control programme in the flock.

For animal treatment only

Adverse events should be reported to the MAPI holder. To report an adverse event, ring +44 7543 556682.

To be supplied only on veterinary prescription.

Legal category:
POM-VPS

Anthelmintic Class:
3-AV

Marketing authorisation number: Vm 43877/4011

Approved 21 December 2023