

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE -**

**VIAL - 50 ml, 250 ml or 500ml**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Dectomax 10 mg/ml Solution for Injection for cattle & sheep

**2. STATEMENT OF ACTIVE SUBSTANCES**

Doramectin 10 mg/ml

Net contents:

50 ml - (0.5g), 250 ml - (2.5g) or 500 ml- (5g)

**3. PHARMACEUTICAL FORM**

Solution for injection.

**4. PACKAGE SIZE**

50 ml, 250 ml or 500 ml

**5. TARGET SPECIES**

Cattle, 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/33kg 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}

**11. SPECIAL STORAGE CONDITIONS**

**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.

POM-VPS

To be supplied only on veterinary prescription.

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

Keep out of the 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 00879/4199

**17. MANUFACTURER'S BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARTON – 50 ml**  
**PLASTIC CONTAINER – 250 ml, 500 ml**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Dectomax 10 mg/ml Solution for Injection for cattle & sheep

**2. STATEMENT OF ACTIVE SUBSTANCES**

Doramectin 10 mg/ml  
Net contents  
50 ml - (0.5g), 250 ml – (2.5g) or 500 ml – (5g)

**3. PHARMACEUTICAL FORM**

Solution for Injection

**4. PACKAGE SIZE**

50 ml

**5. TARGET SPECIES**

Cattle, Sheep

**6. INDICATION(S)**

**Cattle:** Dosage 1 ml/50 kg by subcutaneous injection. For the treatment and control of gastrointestinal roundworms, lungworms, eyeworms, 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.

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**

Read the package leaflet before use.

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 be 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.

**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.

Do not freeze or refrigerate.

Protect from direct sunlight.

Keep the container in the outer carton.

Following the withdrawal of the first dose, use the product within 6 months.

## **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.

POM-VPS

To be supplied only on veterinary prescription.

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

Keep out of the 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 00879/4199

**17. MANUFACTURER’S BATCH NUMBER**

Lot {number}



**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**  
**Dectomax 10mg/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:

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, County Down BT35 6JP,  
United Kingdom

Elanco France S.A.S., 26 rue de la Chapelle, 68330 Huningue, France

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Dectomax 10mg/ml Solution for Injection for cattle & sheep

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

**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)

<i>Ostertagia ostertagi</i>	<i>O. lyrata</i> <sup>1</sup>
(incl. inhibited larvae)	<i>Trichostrongylus axei</i>
<i>Haemonchus placei</i>	<i>Cooperia oncophora</i>
<i>T. colubriformis</i>	<i>C. punctata</i>
<i>C. pectinata</i> <sup>1</sup>	<i>Nematodirus spathiger</i> <sup>1</sup>
<i>C. sumabada</i> (syn. <i>mcmasteri</i> )	<i>Strongyloides papillosus</i> <sup>1</sup>
<i>Bunostomum phlebotomum</i> <sup>1</sup>	<i>Trichuris</i> spp. <sup>1</sup>

*Oesophagostomum radiatum*<sup>1</sup> adults  
Lungworms (adults and fourth stage larvae)  
*Dictyocaulus viviparus*  
Eyeworms (adults)  
*Thelazia* spp.  
Warbles (parasitic stages)  
*Hypoderma bovis*, *H. lineatum*  
Sucking lice  
*Haematopinus euryesternus*, *Linognathus vituli*,  
*Solenopotes capillatus*  
Mange mites  
*Psoroptes bovis*, *Sarcoptes scabiei*

Dectomax injectable solution 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* 28 days and *Psoroptes bovis* 42 days.

To obtain optimal benefit 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 turnout 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 the 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)<sup>1</sup>  
*Oesophagostomum columbianum*  
*Ostertagia (Teladorsagia) circumcincta*\*  
*Strongyloides papillosus*  
*Trichostrongylus axei*  
*T. colubriformis*  
*T. vitrinus*  
*Trichuris* spp. (Adults only)

\* Inhibited larval stages (L4) including strains that are benzimidazole resistant, are also controlled.

<sup>1</sup> 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 anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used. Resistance to 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

## 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 - 25kg	0.75ml
26 - 33 kg	1.0 ml
34 - 41 kg	1.25ml
42 - 50 kg	1.5 ml
51 - 58 kg	1.75ml
59 - 66kg	2.0 ml
67 - 74 kg	2.25 ml
75 - 83 kg	2.5 ml
84 - 91 kg	2.75 ml
92 - 99kg	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 kg 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 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 breached more than 20 times.

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. Do not freeze or refrigerate. Protect from direct sunlight. Following withdrawal of the first dose, use the product within 6 months. 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 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

December 2020

## 15. OTHER INFORMATION

### Legal category:

POM-VPS

To be supplied only on veterinary prescription.

### Anthelmintic Class:

3-AV

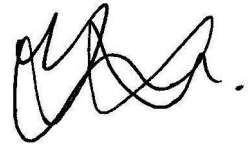
**Package quantities:** Multi-dose vials of 50 ml, 250 ml and 500 ml.

### 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.

**Marketing authorisation number:** Vm 00879/4199

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 23 December 2020