

Registrant:	Pfizer New Zealand Limited, 14 Normanby Road, Mt Eden, Auckland		
Trade Name:	DECTOMAX [®]	ACVM No.:	A006199
Preparation Date:	15 November 2011 (Approved 17 Jan 2012)	Page:	1 of 12
Comments:	Text in the header box will not appear on the final label		

BOTTLE LABEL (NZ)
Main Panel

CAUTION: ECOTOXIC
KEEP OUT OF REACH OF CHILDREN
READ SAFETY DIRECTIONS
FOR ANIMAL TREATMENT ONLY

DECTOMAX[®]
The Performance Formula

DORAMECTIN 10 mg/mL
Injectable Suspension

For the treatment and control of doramectin sensitive internal and external parasites of cattle, sheep and pigs.

200 [500] mL

[Label identifier]

[Pfizer logo]

BOTTLE LABEL
Rear Panel

STORAGE: Store below 30°C (Room Temperature).

BATCH No.:
EXP. DATE:

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BOTTLE LABEL

Side Panel

READ LABEL BOOKLET BEFORE USING THIS PRODUCT

DIRECTIONS FOR USE

Cattle: DOSE: 1 mL per 50 kg of bodyweight by subcutaneous injection (under the skin) into the anterior half of the neck.

Sheep: DOSE: 1 mL per 50 kg of bodyweight by subcutaneous injection (under the skin) into the anterior half of the neck.

Pigs: DOSE: 1mL per 33 kg (0.3 mL per 10kg) of bodyweight by intramuscular injection preferably high on the neck behind the ear.

Choose dose according to the weight of the heaviest animals. Check accuracy of injection equipment regularly.

WITHHOLDING PERIODS

Meat (Cattle, Sheep & Pigs): 35 days

Milk (Cattle & Sheep): 35 days

HANDLING PRECAUTIONS: This material may be harmful if swallowed, inhaled or absorbed through the skin. Avoid ingestion, inhalation and skin contact. Refer to label booklet for further information.

FIRST AID: If swallowed do NOT induce vomiting. For advice, contact the National Poisons Centre 0800 POISON (0800 764 766) or a doctor immediately. Refer to label booklet for further information.

Registered pursuant to the ACVM Act 1997, No. A6199
See www.foodsafety.govt.nz for registration conditions.

[Licenciado no Ministerio da Agricultura sob o nº 4055/92 em 14/08/92.]

[Pfizer logo] Made in Brazil
Pfizer Animal Health
Pfizer New Zealand Limited
Normanby Rd, Mt Eden, Auckland
Technical Services 0800 650 277
® Pfizer registered trademark

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EXTENDED CONTENT LABEL

Top Panel 1

[Arrow graphic]

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EXTENDED CONTENT LABEL

Top Panel 2

BATCH No.:
EXPIRY DATE:

EXTENDED CONTENT LABEL

Top Panel 3

[EAN barcode]

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EXTENDED CONTENT LABEL

Top Panel 4

READ LABEL BOOKLET BEFORE USING THIS PRODUCT

DECTOMAX long acting injectable endectocide is effective against doramectin sensitive gastro-intestinal roundworms (including inhibited larvae of *Ostertagia ostertagi*), lungworms, sucking lice and mange of cattle; and internal and external parasites of sheep and pigs.

DIRECTIONS FOR USE

Cattle: DOSE: 1mL per 50 kg of bodyweight by subcutaneous injection (under the skin) into the anterior half of the neck. Ensure injection is subcutaneous. Intramuscular injection will result in prolonged residues. Where intramuscular injection may have occurred, animals producing meat and offal for human consumption must not be slaughtered within 91 days of the last treatment.

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STORAGE: Store below 30°C (Room Temperature).

Laboratórios Pfizer Ltda. – Animal Health Division
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CNPJ 46.070.868/0001-69

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EXTENDED CONTENT LABEL

Inside Panels

DECTOMAX long acting injectable endectocide is a unique broad spectrum parasiticide for cattle, sheep and pigs of all ages. DECTOMAX is effective in killing internal and external parasites that can cause disease and limit production potential and provides long acting protection against reinfection. The active constituent in DECTOMAX (doramectin) is a novel compound which was discovered and patented by Pfizer. Doramectin is a member of the avermectin/milbemycin family and is effective against internal and external parasites sensitive to this family.

FEATURES

- Effective broad spectrum parasite control.
- Long acting protection against reinfection
- Pain free formulation
- Broad spectrum of activity
- Wide margin of safety in all ages of stock, including young calves, lambs and piglets

PRODUCT DESCRIPTION

DECTOMAX is a colourless to pale yellow, sterile solution which is packed in ready to use, coloured, ultraviolet light resistant glass bottles with an outer, impact resistant container.

HOW DECTOMAX WORKS

The primary mode of action of the active constituent in DECTOMAX (doramectin) is to inhibit the electrical activity that controls nerve cells in nematodes (worms) and muscle cells in arthropods (ticks, mites and lice) causing paralysis and death of the parasite.

INDICATIONS

DECTOMAX has a broad spectrum of activity and is effective in the treatment and control of the internal and external parasites listed below.

Cattle:

- **Adult and immature Gastro-Intestinal Roundworms:** *Ostertagia ostertagi* (including inhibited larvae) - Small brown stomach worm, *O. lyrata*, *Trichostrongylus* sp. - Stomach hair worm, *T. colubriformis* - Black scour worm, *T. longispicularis*¹, *Cooperia oncophora* - Small intestinal worm, *C. punctata*, *C. surnabada (mcmasteri)*, *N. spathiger*¹, *S. papillosus*¹, *Bunostomum phlebotomum*¹ - Hook worm, *Oesophagostomum radiatum* - Nodule worm, *Trichuris* sp.¹
- **Adult and immature Lungworm:** *Dictyocaulus viviparus*
- **Sucking Lice:** *Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*
- **Biting Lice:** Effective as an aid in the control of biting lice (*Bovicola bovis*).
- **Mites:** *Psoroptes natalensis*
- **Long acting protection:** Efficacy trials also demonstrated the following levels of long acting protection against reinfection from the following common and important worm species:

Species:

Ostertagia ostertagi
Cooperia oncophora
Dictyocaulus viviparus
Trichostrongylus axei

Period of Protection Following Treatment:

Up to 28 days
Up to 21 days
Up to 28 days
Up to 21 days

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Oesophagostomum radiatum Up to 21 days
Bunostomum phlebotomum Up to 15 days

Sheep:

- **Gastro-Intestinal Roundworms (Adults and L4 unless otherwise indicated):** *Haemonchus contortus*, *Teladorsagia (Ostertagia) circumcincta*² (including inhibited L4), *T.(O.) trifurcata*, *Trichostrongylus axei*, *T. colubriformis*, *T. vitrinus*, *Cooperia curticei*, *Cooperia oncophora*, *Nematodirus spathiger*, *N. filicollis*, *Chabertia ovina* (adults), *Bunostomum trigonocephalum* (adults), *Trichuris ovis* (adults)
- **Adult and Immature Lungworm:** *Dictyocaulus filaria*
- **Itch Mites:** *Psorergates ovis*
- **Nasal Bot:** *Oestrus ovis* (1st, 2nd and 3rd instar larvae)
- DECTOMAX may also be used as an aid in the prevention of blowfly strike (*Lucilia cuprina*), when used to complement registered flystrike products, as seasonal conditions dictate.

Pigs:

- **Adult and immature Gastro-Intestinal Roundworms:** *Hyostrongylus rubidus* - Red Stomach Worm; *Ascaris suum* - Large Roundworm; *Strongyloides ransomi*¹ - Intestinal Threadworm; *Oesophagostomum dentatum* - Nodule worm; *Oesophagostomum quadrispinulatum*¹ - Nodule worm
- **Adult Lungworms:** *Metastrongylus* spp.
- **Adult Kidney worms:** *Stephanurus dentatus*
- **Sucking Lice:** *Haematopinus suis*
- **Mange Mites:** *Sarcoptes scabiei* var *suis*
- **Persistent protection:** Studies have also demonstrated persistent protection for at least 14 days against reinfection by *Sarcoptes scabiei* var *suis*.

¹ adults only

² Inhibited larval stages (L4) including strains that are benzimidazole resistant, are also controlled.

DIRECTIONS FOR USE

By law the user must take due care, obtaining expert advice when necessary, to avoid unnecessary pain and distress when using the product other than as directed on the label.

Resistance can develop to any anthelmintic. Ask your local veterinary practitioner or animal health adviser for recommended parasite management practices for your area to reduce development of resistance. It is advisable that a resistance test be conducted regularly when using any parasite treatment. If resistance is suspected please advise the manufacturer.

A representative sample of animals should be weighed before treatment either with scales or a weighband. Dose rate to be based on heaviest animal by liveweight for each species by stock class (e.g. for cattle - bulls, cows, calves etc). Do not underdose. Where there is a large variation in size within the group, draft into two or more lines based on bodyweight, to avoid excessive overdosing.

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Cattle:

Administer DECTOMAX at a dosage of 1 mL for every 50 kg of body weight (0.2mg doramectin per kg of body weight) by subcutaneous injection. Ensure injection is subcutaneous. Intramuscular injection will result in prolonged residues. Where intramuscular injection may have occurred, animals producing meat and offal for human consumption must not be slaughtered within 91 days of the last treatment.

Weight (kg)	Dosage (mL)
51-75	1.5
76-100	2
101-150	3
151-200	4
201-250	5
251-300	6
301-350	7

Weight (kg)	Dosage (mL)
351-400	8
401-450	9
451-500	10
501-550	11
551-600	12
601-650	13

Cattle heavier than 650 kg should be dosed at 1 mL per 50 kg.

Sheep:

Administer DECTOMAX at a dosage of 1 mL for every 50 kg of body weight (0.2 mg doramectin per kg of body weight) by subcutaneous injection. Where intramuscular injection may have occurred, animals producing meat and offal for human consumption must not be slaughtered within 35 days of the last treatment.

Weight (kg)	Dosage (mL)
15-20	0.4
20-25	0.5
25-30	0.6
30-35	0.7
35-40	0.8
40-45	0.9

Weight (kg)	Dosage (mL)
45-50	1.0
50-55	1.1
55-60	1.2
60-65	1.3
65-70	1.4
70-75	1.5

Animals heavier than 75 kg to be dosed at 0.2 mg/kg (0.1 mL/5 kg) bodyweight.

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. Assess bodyweight as accurately as possible before calculating dosage. Administer the calculated dose accurately, particularly when treating young lambs.

Pigs:

Administer DECTOMAX by intramuscular injection into the neck region and preferably high up behind the ear. A single treatment of 0.3 mL per 10 kg bodyweight (1 mL per 33 kg) should be given. Pigs should be weighed with either scales or a weighband. Piglets weighing 16 kg or less should be dosed in accordance with the following table:

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Weight (kg)	Dosage (mL)
5-7	0.2
8-10	0.3
11-13	0.4
14-16	0.5

SAFETY

During extensive field trials, Dectomax was proven to have a wide margin of safety when administered to cattle, sheep and pigs of all ages, including young calves and lambs, and at all stages of the swine reproductive cycle. The product has also been specially formulated to eliminate the risk of injection site pain after administration.

WITHHOLDING PERIODS

It is an offence for users of this product to cause residues exceeding the relevant MRL in the NZ (Maximum Residues Limits of Agricultural Compounds) Food Standards.

Meat (Cattle, Sheep and Pigs): Animals producing meat and offal for human consumption must not be sold for slaughter either during treatment or within 35 days respectively of cessation of the last treatment.

Milk (Cattle & Sheep): Milk intended for sale for human consumption must be discarded during treatment for not less than 35 days following the last treatment.

ADMINISTRATION

Before using DECTOMAX it is important that administration equipment is properly prepared so as to avoid malfunction. Use dry sterile equipment and follow aseptic procedures. To ensure no problems are experienced, the following steps should be taken:

1. Remove the protective cap from the DECTOMAX bottle and sterilise the exposed rubber stopper by wiping with disinfectant.
2. Hold the bottle upright and insert the draw off needle firmly into the centre of the rubber stopper then push the securing device over the bottle neck.
3. Prime the injector unit before use.

Administer DECTOMAX into the anterior neck region and preferably high up behind the ear. Animals should be restrained to ensure that treatment can be properly administered. When the temperature of the injectable solution is below 5°C, its viscosity increases and increased effort may be required for injecting. Syringeability can be improved by gently warming the injecting equipment and the product to 15°C.

[Graphic showing application sites]

Caution: To avoid infection leading to carcass damage the following steps should be observed.

1. Sterilise all injection apparatus by boiling (or equivalent) before use (not disposable plastic syringes). Dry equipment thoroughly before use. Avoid use of strong disinfectants on apparatus.
2. Maintain cleanliness at all times.
3. Keep needles sharp, clean and dry. Replace frequently.

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4. Use needles of appropriate gauge and length. For subcutaneous (SC) administration, use only sterile 16 -18 gauge needles which are 15 mm in length.
5. As far as possible avoid injection of animals during wet weather or under dusty conditions.
6. Intramuscular (IM) injections in pigs should be made into muscle tissue on the side of the neck. Subcutaneous (SC) injections in cattle and sheep should be made under the skin high on the neck behind the ear.

OPERATOR WARNING

This material may be harmful to humans if swallowed, inhaled or absorbed through the skin and may affect fertility, foetal development, breast-fed children or the liver if ingested repeatedly at high doses. Avoid skin contact, inhalation and ingestion. Wash hands and exposed skin immediately after use. This material is very toxic to aquatic organisms and terrestrial invertebrates, and is harmful to the soil environment.

FIRST AID

If swallowed do NOT induce vomiting. For advice, contact the National Poisons Centre 0800 POISON (0800 764 766) or a doctor immediately. If skin or hair contact occurs, remove contaminated clothing and flush skin or hair with running water. If splashed in eyes, wash out immediately with water.

DISPOSAL

Preferably dispose of product by use, otherwise dispose of product and packaging at an approved landfill, or other approved facility. Avoid contamination of any water supply with product or empty container.

SPILLAGE

Wear appropriate protective clothing and prevent material from entering waterways. Absorb spills with inert material and place in waste containers. Sweep up solids without creating dust. Wash area with water and absorb with further inert material. Dispose of waste safely.

STORAGE

Store below 30°C (Room Temperature).

PACKAGING INFORMATION

DECTOMAX is available in 200 mL and 500 mL multi-dose packs.

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TREATMENTS PER PACK

As a quick reference, treatments per pack are tabled below:

Cattle:

Animal Weight (kg)	Treatments per Pack	
	200 mL	500 mL
50	200	500
100	100	250
150	66	166
200	50	125
250	40	100
300	33	83
350	28	71

Animal Weight (kg)	Treatments per Pack	
	200 mL	500 mL
400	25	62
450	22	55
500	20	50
550	18	45
600	16	42
650	15	38

Sheep:

Animal Weight (kg)	Treatments per Pack	
	200 mL	500 mL
15	666	1665
20	500	1250
25	400	1000
30	333	832
35	285	712
40	250	625
45	222	555

Animal Weight (kg)	Treatments per Pack	
	200 mL	500 mL
50	200	500
55	181	452
60	166	415
65	153	382
70	142	355
75	133	332

Pigs:

Animal Weight (kg)	Treatments per Pack	
	200 mL	500 mL
33	200	500
66	100	250
99	66	166
132	50	125
165	40	100
198	33	83

Animal Weight (kg)	Treatments per Pack	
	200 mL	500 mL
231	28	71
264	25	62
297	22	55
330	20	50
363	18	45

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EXTENDED CONTENT LABEL

Base Panel 1

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EXTENDED CONTENT LABEL

Base Panel 2

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