

Product Name: DECTOMAX INJECTABLE ENDECTOCIDE	
Date: 22 September 2011	Page 1 of 18
Product Size: 200 mL, 500 mL	Description: Composite label
File number: LAB0015 - Dectomax Injectable Sept (2) 2011 in-use final.doc	Version: version 3
Reason: Category 14 – Addition of In-use shelf life and ESI Statement	

Text above this line and in italics between parallel lines is not included in the label copy.

IMMEDIATE CONTAINER (Bottle)
Front Panel

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



RLP
Approved



DECTOMAX[®]
Injectable endectocide

DORAMECTIN 10 mg/mL

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

200 mL/500 mL

CODE



IMMEDIATE CONTAINER (Bottle)
Left Panel

READ OUTER CONTAINER ZIP SEAL LABEL BEFORE USING THIS PRODUCT

DIRECTIONS FOR USE

Restraints:

DO NOT USE in cattle during lactation or less than 60 days before calving when milk or milk products are to be used for human consumption or processing.

DO NOT USE in animals within 28 days (4 weeks) of a previous treatment.

Dosage and Administration

Use contents within 28 days of first broaching of the vial. Store upright.

Discard the unused portion.

Cattle: 1mL per 50 kg of bodyweight S/C

PFIZER ANIMAL HEALTH

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Pigs: 1mL per 33 kg (0.3 mL per 10kg) of bodyweight I/M.

NOT TO BE USED FOR ANY PURPOSE OR IN ANY MANNER CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.

WITHHOLDING PERIODS

MEAT - CATTLE 42 DAYS; PIGS 35 DAYS.

MILK- Do not use during lactation or less than 60 days before calving when milk or milk products are to be used for human consumption or processing.

TRADE ADVICE

EXPORT SLAUGHTER INTERVAL (ESI): DO NOT USE less than 42 days before slaughter for export. The ESI on this label was correct at the time of label approval. Before using this product, confirm the current ESI with the manufacturer on 1800 814 883 or the APVMA website (www.apvma.gov.au/residues/).

SAFETY DIRECTIONS: Poisonous if swallowed. Avoid contact with skin.

FIRST AID: If poisoning occurs contact a doctor or Poisons Information Centre.
Phone Australia 131126

Licenciado no Ministério da Agricultura sob Nº 4055/92 em 14/08/92.



Made in Brazil
Animal Health
A division of Pfizer Australia Pty Ltd
Wharf Rd West Ryde NSW 2114
Toll Free Information Line 1800 022 442

® Registered
Trademark
CODE

APVMA Approval No.: 46128/51784
Store below 30°C (Room Temperature)

Batch No:

Exp. Date

PFIZER ANIMAL HEALTH

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ZIP SEAL LABEL (Plastic Container)
Top Panel - Right Section

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DECTOMAX[®]
Injectable endectocide

DORAMECTIN 10 mg/mL

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

200 mL/500 mL



Batch No:
Expiry Date

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ZIP SEAL LABEL (Plastic Container)

Top Panel - Central Section

DIRECTIONS FOR USE

READ ZIP SEAL LABEL BOOKLET BEFORE USING THIS PRODUCT

Restraints:

DO NOT USE in cattle during lactation or less than 60 days before calving when milk or milk products are to be used for human consumption or processing.

DO NOT USE in animals within 28 days (4 weeks) of a previous treatment.

Dosage and Administration

Use contents within 28 days of first broaching of the vial. Store upright.

Discard the unused portion.

Cattle: 1 mL per 50 kg of bodyweight S/C

Pigs: 1 mL per 33 kg (0.3 mL per 10 kg) of bodyweight I/M

WITHHOLDING PERIODS

Cattle:

MEAT - DO NOT USE less than 42 days before slaughter for human consumption.

MILK - DO NOT USE during lactation or less than 60 days before calving when milk or milk products are to be used for human consumption or processing.

Pigs: **DO NOT USE** less than 35 days before slaughter for human consumption.

TRADE ADVICE

EXPORT SLAUGHTER INTERVAL (ESI): DO NOT USE less than 42 days before slaughter for export. The ESI on this label was correct at the time of label approval. Before using this product, confirm the current ESI with the manufacturer on 1800 814 883 or the APVMA website (www.apvma.gov.au/residues/),

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

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ZIP SEAL LABEL (Plastic Container)

Top Panel - Left Section

Cattle: Dectomax Injectable Endectocide is for the treatment and control of doramectin sensitive internal and external parasites of cattle, providing persistent protection against reinfection by Small Brown Stomach worm, Stomach Hair worm, Small Intestinal worm, Barber's Pole worm, Hookworm, Nodule worm, Lungworm and Cattle Tick.

Pigs: Dectomax Injectable Endectocide is for the treatment and control of doramectin sensitive internal and external parasites of pigs, providing persistent protection against reinfection by *Ascaris suum* and mange mite.

SAFETY DIRECTIONS: Poisonous if swallowed. Avoid contact with skin.

FIRST AID: If poisoning occurs contact a doctor or Poisons Information Centre. Phone Australia_131126.

Additional information is listed in the Material Safety Data Sheet.

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ZIP SEAL LABEL (Plastic Container)

Inside Page 1

INTRODUCTION: Dectomax Injectable Endectocide is a broad spectrum parasiticide for cattle and pigs of all ages. Dectomax is effective in killing internal and external parasites that can cause disease and limit production potential. The active constituent in Dectomax (doramectin) is a member of the macrocyclic lactone family of chemicals and was discovered and patented by Pfizer.

FEATURES:

- Effective broad spectrum parasite control.
- Persistent protection in cattle against reinfection by Small Brown Stomach Worm, Stomach Hair worm, Small Intestinal worm, Barbers Pole worm, Hookworm, Nodule worm, Lungworm and Cattle Tick, and *Ascaris suum* and mange mite in pigs.
- Non-irritant formulation.
- Wide margin of safety in all ages of stock, including young calves and piglets.

PRODUCT DESCRIPTION: Dectomax is a colourless to pale yellow, sterile solution which is packed in ready to use, coloured, ultra violet light resistant glass bottles. It is formulated to deliver the recommended dosage at a rate of 1mL for every 50 kg of body weight (200 µg doramectin per kg of body weight) when administered by subcutaneous (S/C) injection to cattle, or at 0.3 mL for every 10 kg (1 mL per 33 kg) of bodyweight (300 µg doramectin per kg of body weight)) when administered by intramuscular (I/M) injection to pigs.

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 (lice, ticks) causing paralysis and death of the parasite.

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Inside Page 2

CATTLE

PARASITES WHICH DECTOMAX IS EFFECTIVE AGAINST

Dectomax has a broad spectrum of activity. It was effective in the treatment and control of the following species in Australian trials:

Adult and immature Gastrointestinal Roundworms:

Ostertagia ostertagi (including inhibited larvae) - Small brown stomach worm

Haemonchus placei - Barber's pole worm

Trichostrongylus axei - Stomach hair worm

T. colubriformis - Black scour worm

*T. longispicularis*¹

Cooperia oncophora - Small intestinal worm

Cooperia spp

*Bunostomum phlebotomum*¹ - Hook worm

Oesophagostomum radiatum - Nodule worm

*Toxocara vitulorum*¹ - Round worm

¹ adults only

Adult and immature Lungworm:

Dictyocaulus viviparus

Sucking Lice:

Linognathus vituli

Solenopotes capillatus

Haematopinus eurysternus

Biting Lice:

Effective as an aid in the control of biting louse (*Bovicola bovis*).

Cattle Tick (*Boophilus microplus*)

For the treatment and control of doramectin sensitive cattle tick, including synthetic pyrethroid, organophosphorus and amidine resistant strains. The persistence of doramectin prevents the development of viable cattle ticks for a period of 28 days.

Mange Mites: *Chorioptes bovis*; *Sarcoptes scabiei* var *bovis*¹

¹Not present in Australia

Persistent Protection:

Australian trials also demonstrated the following levels of persistent protection against reinfection from seven common and important worm species.

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Species	Period of protection following treatment
<i>Ostertagia ostertagi</i>	Up to 21 days
<i>Cooperia oncophora</i>	Up to 14 days
<i>Cooperia</i> spp	Up to 21 days
<i>Haemonchus placei</i>	Up to 21 days
<i>Dictyocaulus viviparus</i>	Up to 28 days
<i>Oesophagostomum radiatum</i>	Up to 21 days
<i>Trichostrongylus axei</i>	Up to 21 days
<i>Bunostomum phlebotomum</i>	Up to 21 days

SAFETY OF DECTOMAX – CATTLE: During extensive field trials, Dectomax was proven to have a wide margin of safety when administered to cattle of all ages, including young calves. The product has also been specially formulated to minimise the risk of injection site pain after administration.

DIRECTIONS FOR USE

Restraints:

DO NOT USE in cattle during lactation or less than 60 days before calving when milk or milk products are to be used for human consumption or processing.

DO NOT USE in animals within 28 days (4 weeks) of a previous treatment.

Precautions:

To avoid tissue residues, take care to estimate the weights and dosages in young animals.

Cattle Tick Control: The persistence of doramectin prevents the development of viable cattle ticks for a period of 28 days following treatment. However, engorged female ticks that drop off for up to 3 days after treatment may lay viable eggs and this should be taken into account when planning a strategic tick control program. If presenting cattle for clearance to tick free areas, consult your local tick advisory authority before use.

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Dosage and Administration

**Use contents within 28 days of first broaching of the vial. Store upright.
Discard the unused portion.**

Administer Dectomax by subcutaneous (S/C) injection (under the skin) into the neck region and preferably high up behind the ear. Use the dose rate, according to the weight of the animal, given in the tables below. Dose rate to be based on the heaviest cattle in each group (bulls, cows, steers, 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. A representative sample of animals should be weighed before treatment either with scales or a weighband.

DOSE RATE - CATTLE:

1 mL per 50 kg bodyweight subcutaneously (S/C) (under the skin)

Weight (kg)	Dose (mL)	Weight (kg)	Dose (mL)
40-50	1	301-350	7
51-75	1.5	351-400	8
76-100	2	401-450	9
101-150	3	451-500	10
151-200	4	501-550	11
201-250	5	551-600	12
251-300	6	601-650	13

Cattle in excess of 650 kg should be dosed at 1mL per 50kg bodyweight.

A representative sample of animals should be weighed before treatment either with scales or a weighband.

Dose rate to be based on the heaviest cattle in each group (bulls, cows, steers, calves etc)

Where there is a large variation in size within the group, draft into two or more lines based on bodyweight, to avoid excess overdosing.

Treatment of very young animals (less than 40 kg bodyweight) is generally not warranted.

Worm parasites may develop resistance to any anthelmintic. If this is suspected please contact your local veterinary practitioner or advise the manufacturer.

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PIGS

PARASITES WHICH DECTOMAX IS EFFECTIVE AGAINST

Dectomax has a broad spectrum of activity. It is effective in the treatment and control of the following parasite species:

Adult and immature Gastro-Intestinal Roundworms:

- Hyostromylus rubidus* Red Stomach Worm
 - Ascaris suum* - Large Roundworm
 - Strongyloides ransomi*¹ Intestinal Threadworm
 - Oesophagostomum dentatum* - Nodule worm
 - Oesophagostomum quadrispinulatum* - Nodule worm
 - Trichuris suis*¹ - Whipworm
- ¹ adults only

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 the following levels of persistent protection against reinfection:

Species	Period of protection following treatment
<i>Ascaris suum</i>	At least 7 days
<i>Sarcoptes scabiei</i> var <i>suis</i>	At least 18 days

SAFETY OF DECTOMAX – PIGS: During extensive field trials, Dectomax was proven to have a wide margin of safety when administered to pigs of all ages and at all stages of the reproductive cycle. The product has also been specially formulated to minimise the risk of injection site pain after administration.

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ZIP SEAL LABEL (Plastic Container)

Inside Page 6

DIRECTIONS FOR USE

Restraints:

DO NOT USE in animals within 28 days (4 weeks) of a previous treatment.

Precautions:

To avoid tissue residues, take care to estimate the weights and dosages in young animals.

Dosage and Administration

Use contents within 28 days of first broaching of the vial. Store upright. Discard the unused portion.

Administer Dectomax by intramuscular (I/M) 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:

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

Worm parasites may develop resistance to any anthelmintic. If this is suspected please contact your local veterinary practitioner or advise the manufacturer.

General Directions

Before using Dectomax it is important that administration equipment is properly prepared so as to avoid malfunction. Use dry, sterile syringes and needles and aseptic procedures when withdrawing and administering Dectomax. 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.

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Administer Dectomax subcutaneously (S/C) in cattle or intramuscularly (I/M) in pigs into the neck region and preferably high up behind the ear. As an alternative, anywhere on the neck away from valuable carcass muscle is suitable. 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.

DIAGRAM OF APPLICATION SITE

Caution - avoid carcass damage

- (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.
- (4) Use needles of appropriate gauge and length. For subcutaneous (S/C) administration, use only sterile, dry 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 (I/M) injections in pigs should be made into muscle tissue on the side of the neck. Subcutaneous (S/C) injections in cattle should be made under the skin high on the neck behind the ear.

NOT TO BE USED FOR ANY PURPOSE OR IN ANY MANNER CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.

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WITHHOLDING PERIODS:

Cattle:

MEAT- DO NOT USE less than 42 days before slaughter for human consumption.

MILK- DO NOT USE during lactation or less than 60 days before calving when milk or milk products are to be used for human consumption or processing.

Pigs: DO NOT USE less than 35 days before slaughter for human consumption.

TRADE ADVICE

EXPORT SLAUGHTER INTERVAL (ESI): DO NOT USE less than 42 days before slaughter for export. The ESI on this label was correct at the time of label approval. Before using this product, confirm the current ESI with the manufacturer on 1800 814 883 or the APVMA website (www.apvma.gov.au/).

SAFETY DIRECTIONS: Poisonous if swallowed. Avoid contact with skin.

FIRST AID: If poisoning occurs, contact a doctor or Poisons Information Centre. *Phone Australia 131126.*

Additional information is in the Material Safety Data Sheet.

PROTECTION OF FISH, CRUSTACEANS AND THE ENVIRONMENT:

Doramectin is extremely toxic to aquatic species. Do not contaminate dams, rivers, streams or other waterways with the chemical or used container.

When used according to label instructions, Dectomax Injectable Endectocide is not likely to have an unintended effect that is harmful to the environment or have an overall adverse impact on dung beetle populations. Increased mortality and impaired development of larvae may be expected, but for a limited period after treatment.

Dispose of empty container by wrapping with paper and putting in garbage.

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

PACKAGING INFORMATION: Dectomax is available in 200 mL and 500 mL multidose 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
400	25	62
450	22	55
500	20	50
550	18	45
600	16	42
650	15	38

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
231	28	71
264	25	62
297	22	55
330	20	50
363	18	45

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DIRECTIONS FOR USE

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Restraints:

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DO NOT USE in animals within 28 days (4 weeks) of a previous treatment.

Dosage and Administration

Use contents within 28 days of first broaching of the vial. Store upright. Discard the unused portion.

Cattle: 1 mL per 50 kg of bodyweight S/C

Pigs: 1 mL per 33 kg (0.3 mL per 10 kg) of bodyweight I/M

WITHHOLDING PERIODS:

Cattle:

MEAT - DO NOT USE less than 42 days before slaughter for human consumption.

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SAFETY DIRECTIONS: Poisonous if swallowed. Avoid contact with skin.

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