PACKAGE LEAFLET

Dectomax 10mg/ml Solution for Injection for Pigs

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

Marketing authorisation holder:

To be completed nationally

Manufacturer responsible for batch release:

Elanco France S.A.S
26 Rue de la Chapelle
68330 Huningue
France

Norbrook Laboratories Ltd,
Station Works,
Newry BT35 6JP
Northern Ireland, UK

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dectomax 10 mg/ml Solution for Injection for Pigs (UK)
Dectomax S Injektionslösung 10 mg / ml Lösung für Schweine(DE)

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

1 ml Dectomax 10 mg/ml Solution for Injection contains the following:

Active substance:	Doramectin	10 mg
Excipient(s):	Butylhydroxyanisole	0.1 mg

4. INDICATION(S)

For treatment of mange mites, gastrointestinal roundworms, lungworms, kidney worms and sucking lice in pigs.

Gastrointestinal nematodes (adults and fourth stage larvae)
- *Hyostrongylus rubidus*
- *Ascaris suum*
- *Strongyloides ransomi (adults only)*
- *Oesophagostomum dentatum*
- *Oesophagostomum quadrispinulatum*

Lungworms
- *Metastrongylus spp. (adults only)*

Kidney worms
Stephanurus dentatus (adults only)

Sucking Lice
Haematopinus suis

Mange Mites
Sarcoptes scabiei

Dectomax injection for pigs protects pigs against infection or reinfection with *Sarcoptes scabiei* for 18 days.

5. CONTRAINDICATIONS

Dectomax Injection for pigs should not be used in dogs, as severe adverse reactions may occur. In common with other avermectin, certain breeds of dog, such as collies, are especially sensitive and particular care should be taken to avoid accidental consumption of the product.

6. ADVERSE REACTIONS

None have been observed.
If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs.

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

Administer Dectomax injection for pigs by the intramuscular route at a dosage of 0.3 ml/10 kg bodyweight (1 ml per 33 kg) equivalent to 0.3 mg doramectin per kg bodyweight.

Piglets weighing 16 kg or less should be dosed in accordance with the following table:

Body weight (kg)	**Dose (mL)**
Less than 4 kg	0.1 mL
5-7 kg	0.2 mL
8-10 kg	0.3 mL
11-13 kg	0.4 mL
14-16 kg	0.5 mL

9. ADVICE ON CORRECT ADMINISTRATION

Each injection should be made into the neck region using a dry, sterile 16 to 18 gauge needle, 20-25 mm in length. When the temperature of the formulation is below 5^0 C, syringeability may be improved by gently warming the injecting equipment and the product.
When treating groups of animals, use only the appropriate Dectomax automatic dosing device and vented draw-off apparatus.
For the treatment of individual pigs, seek veterinary advice regarding the use of appropriate sized needles and disposable syringes. For the treatment of piglets weighing 16 kg or less, a 1 ml disposable syringe graduated in increments of 0.1 ml or less should be used.
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.

10. WITHDRAWAL PERIOD

Meat and offal: 77 days.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 30º C. Do not refrigerate or freeze. Protect from direct sunlight – do not remove from the protective plastic. Following withdrawal of the first dose, use the product within 28 days. Discard unused material after this time. When the container is broached for the first time, the date on which any product remaining in the container should be discarded, should be calculated. This discard date should be written in the space provided on the label. Do not use after the expiry date stated on the carton and vial label after "EXP".
Keep out of the reach and sight of children.

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 and sheep.

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

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.

Wash hands after use. Do not smoke or eat while handling the product. Take care to avoid accidental self-administration – seek medical attention should any specific signs be noticed.

Advice to Medical Practitioners: In cases of accidental self injection specific symptoms have rarely been observed and therefore any cases should be treated symptomatically.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, 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

To be inserted.

15. OTHER INFORMATION

Dectomax injection for pigs is a ready-to-use, colourless to pale yellow, sterile oily solution containing 1% w/v doramectin (10 mg/ml). The product also contains 0.01% butylated hydroxyanisoleas an antioxidant preservative. The recommended dosage is 300 µg/kg bodyweight given by intramuscular injection, i.e. 0.3 ml/10 kg bodyweight (1ml per 33kg).

Product characteristics: Dectomax injection for pigs is a highly active, broad-spectrum parasiticide for parenteral administration to pigs. It contains doramectin, a novel fermentation-derived compound discovered by Pfizer. Doramectin is isolated from fermentations of selected strains derived from the soil organism *Streptomyces avermitilis.*
A primary 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
Broad-spectrum: one low-volume dose of Dectomax injection for pigs effectively treats and controls a wide range of nematode and arthropod parasites that impair health and productivity of pigs.

Long-action: the sustained drug concentrations that results from its unique pharmacokinetics enable the product to protect cattle against parasite infection and reinfection for extended periods following treatment.

Safety: Dectomax injection for pigs has a wide margin of safety in all categories of pigs.

Dectomax injection for pigs is available in 50 ml, 250 ml and 500 ml multi-dose, rubber capped vials. Not all pack sizes may be marketed.