SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dectomax 10 mg/ml Solution for Injection for Pigs (UK)
Zearl 10 mg/ml Solution for Injection for Pigs (IE)
Zearl porcs (FR)
Dectomax 10 mg/ml Solution Injectable Pour Porcs (BE, LU)
Dectomax S Injektionslösung 10 mg / ml Lösung für Schweine (DE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Active substance:

Doramectin	10 mg(1)

Excipient(s):

Butylhydroxyanisole (E320)	0.1 mg

(1) Contains no overage and assumes a potency of 100 percent. The actual amount of doramectin added will depend on the potency of the ingoing drug substance.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Colourless to pale yellow sterile oily solution.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

The product has been formulated specifically for pigs. It should not be administered to other species as severe adverse reactions, including fatalities in dogs, may occur. Do not use in case of hypersensitivity to the active substance or any of the excipients.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

i) Special precautions for use in animals

Avermectins may not be well tolerated in all non-target species. Cases of intolerance with fatal outcome are reported in dogs, especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles/tortoise. Care should be taken to avoid ingestion of spilled product or access to containers by these other species.

When treating groups of animals, use a suitable automatic dosing device and vented draw-off apparatus.

For treatment of individual pigs, the use of appropriate sized needles and disposable syringes should be advised by a veterinarian. For the treatment of piglets weighing 16kg or less, a 1mL disposable syringe graduated in increments of 0.1mL or less should be used.

Use dry, sterile equipment and follow aseptic procedures. Avoid introduction of contamination. Vial stoppers must not be broached more than 20 times. Swab the septum before removing each dose.

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

Read package insert before use.
Do not smoke or eat while handling the product. Wash hands after use.
Take care to avoid accidental self-administration – seek medical attention should any specific signs be noticed.
Advice to medical practitioners: In case of accidental self injection specific symptoms have rarely been observed and therefore any cases should be treated symptomatically.

iii) Other precautions

Doramectin is very toxic to dung fauna and aquatic organisms and may accumulate in sediments.

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.

4.6 Adverse reactions (frequency and seriousness)

None have been observed.

4.7 Use during pregnancy, lactation or lay

The product is indicated for use in breeding and lactating sows and in breeding boars.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

A single treatment of 0.3 ml (3 mg doramectin) per 10 kg bodyweight, (1ml per 33 kg) equivalent to 300 μg/kg bodyweight, administered by intramuscular injection.

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

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Overdoses up to 10 times the label recommended dose resulted in no clinical signs that could be attributed to treatment with doramectin.

4.11 Withdrawal period

Meat and offal: 77 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiparasitic Products Insecticides and Repellents/Endectocides
ATCvet Code: QP 54AA03

5.1 Pharmacodynamic properties

Doramectin is an antiparasitic agent, isolated from fermentation of selected strains derived from the soil organism *Streptomyces avermitilis*. It is a macrocyclic lactone and is closely related to ivermectin. Both compounds share a wide spectrum of antiparasitic activity and produce a similar paralysis in nematodes and parasitic arthropods. Macrocyclic lactones activate glutamate gated chloride channels (GluCl) found on muscle membranes of the pharynx and particular neurones of invertebrate parasites. The selective toxicity of the macrocyclic lactones as antiparasitics is attributed to this action on channels that are not present in the host animal. There is evidence that the membranes of the muscle cells of the invertebrate female reproductive tract may be more sensitive to macrocyclic lactones than receptors on nerve or other muscle and this may explain the dramatic but temporary reduction in egg production in parasites not killed or eliminated by drug therapy.

5.2 Pharmacokinetic particulars

Maximum plasma concentration of doramectin occurs in pigs 3 days after intramuscular administration of the product. The elimination half-life is around six days.

5.3 Environmental properties

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.

Doramectin is very toxic to aquatic organisms and may accumulate in sediments.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole (E320)
Ethyl oleate
Sesame oil

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Dectomax will be supplied in:
Opaque plastic overwrapped vial of 50 ml
Opaque plastic overwrapped vial of 250 ml
Opaque plastic overwrapped vial of 500 ml
Consisting of multi-dose, rubber capped, amber glass vials containing a clear colourless to pale yellow, sterile oily solution.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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.

7. MARKETING AUTHORISATION HOLDER

8. MARKETING AUTHORISATION NUMBER

9. DATE OF RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

Date: January 2014

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.


23 January 2014