IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10999/028/001A**
Case No: 7006374

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Norbrook Laboratories Limited

Station Works, **Newry**, **Co. Down BT35 6JP**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Devomycin D Solution for Injection

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation,unless revoked, shall continue in force from **03/07/2009**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Devomycin D Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:	
Active substance	
Streptomycin as Streptomycin Sulphate	120,000 Units
Dihydrostreptomycin as Dihydrostreptomycin Sulphate	120,000 Units
Excipients	
Sodium Metabisulphite (E223)	1 mg
Chlorocresol	1 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle
Sheep
Pigs

4.2 Indications for use, specifying the target species

Devomycin D Injection is indicated in the treatment of infections caused by organisms sensitive to Streptomycin and Dihydrostreptomycin in cattle, sheep and pigs. It is also indicated in the treatment of Leptospirosis in cattle and pigs.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substances.
Do not use in sheep producing milk for human consumption.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Take particular care when treating animals suffering from renal damage.

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

None.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

Administer by intramuscular injection.
A daily dose rate of 10,000 units per kg bodyweight (1 ml/24 kg) is recommended for up to three days.

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

Excessive and prolonged administration may cause renal damage and can lead to interference with balance and hearing. In extreme cases the damage can be permanent.

4.11 Withdrawal Period(s)

Meat and offal: 21 days

Milk:
Cattle: 48 hours
Do not use in ewes producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinfectives for systemic use, aminoglycoside antibacterials
ATCvet code: QJ01GA01 + QJ01GA90

5.1 Pharmacodynamic properties

Dihydrostreptomycin and Streptomycin are aminoglycosides and are thought to act by entering the bacterial cell and combining irreversibly with ribosomal RNA. This combination interferes with protein synthesis including misreading of the amino acid sequence and premature termination of the protein chain, resulting in the death of the bacteria.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Citrate
Sodium Metabisulphite (E223)
Citric Acid
Chlorocresol
Water for Injections

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 12 months.
Shelf-life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Store in a refrigerator (2°C-8°C).
Protect from light.

6.5 Nature and composition of immediate packaging

Devomycin D is packaged in amber Type II glass vials of 50 and 100 ml and sealed using bromobutyl rubber bungs and aluminium caps.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited,
Station Works,
Newry,
Co. Down, BT35 6JP,
Northern Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10999/028/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT

3rd July 2009