IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10999/029/001A**
Case No: 7005018

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 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 previously revoked, shall continue in force from **01/10/2008**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, 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 Solution for Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:	
Active substance	
Streptomycin	200,000 units
as Streptomycin Sulphate	
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.
A pale yellow aqueous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle
Sheep
Pigs

4.2 Indications for use, specifying the target species

Devomycin Injection is indicated in the treatment of infections caused by organisms sensitive to Streptomycin in cattle, sheep and pigs. It is also indicated in the treatment of actinobacillosis (wooden tongue) in cattle and leptospirosis in cattle and pigs.

4.3 Contraindications

Contra-indicated in cases of known hypersensitivity to the active ingredient.
Do not use in sheep producing milk for human consumption.

4.4 Special warnings for each target species

No special warnings.

4.5 Special precautions for use

Special precaution(s) for use in animals

Take particular care when treating animals suffering from renal damage.

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

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

None.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Devomycin Injection can be safely administered during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

To ensure a correct dosage body weight should be determined as accurately as possible.
Administer to cattle, sheep and pigs by intramuscular injection. A daily dose rate of 10,000 units per kg bodyweight (1ml/20kg) is recommended for up to three days.
The maximum dose volume to be administered at a single site in cattle is 10 ml.

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

Excessive and prolonged administration can lead to interference with balance and hearing. In extreme cases the damage can be permanent.
Streptomycin is known to be nephrotoxic therefore particular care should be taken when treating animals suffering from renal damage.

4.11 Withdrawal Period(s)

Cattle:
Meat and offal: 12 days
Milk: 48 hours

Pigs and Sheep:
Meat and offal: 18 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Phamacotherapeutic group: Antibacterials for systemic use, streptomycin.
ATCvet code: QJ01GA01

5.1 Pharmacodynamic properties

Streptomycin is a member of the aminoglycoside group of antibiotics and is 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)
Chlorocresol
Citric Acid
Water for Injection

6.2 Incompatibilities

Do not dilute or mix with other compounds.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf-life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25^0C.

6.5 Nature and composition of immediate packaging

Packaged in Amber Type II glass vials of 50 ml and 100 ml, sealed with bromobutyl rubber bungs and aluminium unlacquered caps.
Not all pack sizes may be marketed.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10999/029/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2003/ 30th September 2008