SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Devomycin 250mg/ml Solution for Injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Each ml contains:

Streptomycin Sulphate	250 mg.

Excipients:

Chlorocresol	1.0 mg
Sodium Metabisulphite	1.0 mg

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for Injection.
A clear pale yellow sterile aqueous antibiotic solution

4. CLINICAL PARTICULARS

4.1 Target species

Horses
Cattle
Sheep
Dogs
Cats

4.2 Indications for use, specifying the target species

Devomycin Injection is active against a wide range of Gram-negative organisms and some Gram-positive pathogens. Devomycin Injection is indicated in the treatment of infections caused by organisms sensitive to Streptomycin including *E.coli*, *Klebsiella spp*., and some species of *Proteus*, *Pasteurella* and *Salmonella*.

4.3 Contraindications

Contra-indicated in cases of known hypersensitivity to the active ingredients.

4.4 Special Warnings for each target species

No special warnings.

4.5 Special precautions for use

Use of the product should be based on susceptibility testing of 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 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

Do not handle this product if you are sensitised (allergic) to aminoglycoside antibiotics.

Care should be taken to avoid accidental self-injection. In case of accidental injection seek medical advice.

In case of accidental contact with skin or eyes, wash the affected area with plenty of water immediately.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None.

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

Concurrent use with other potentially nephrotoxic drugs, such as diuretics, should be avoided.

4.9 Amounts to be administered and administration route

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

For intramuscular injection only.
The injection site should be massaged after administration.

Horses, cattle and sheep: 10 mg Streptomycin/kg bodyweight (1 ml/25 kg bodyweight) for up to 3 days.
For cattle, the maximum dose volume to be administered at a single site is 10 ml and for sheep 5 ml.
Dogs and cats: 25 mg Streptomycin/kg bodyweight (1 ml/10 kg bodyweight)

Care should be taken in computing the dose to avoid overdosage.

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. Cats are the most susceptible animals.

4.11 Withdrawal period

Cattle
Meat and Offal – 16 days
Milk – 48 hours

Sheep
Meat and Offal – 18 days
Do not use in sheep producing milk intended for human consumption.

Horses
Not to be used in horses intended for human consumption.

Treated horses may never be slaughtered for human consumption.

The horse must have been declared as not intended for human consumption under national horse passport legislation.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Aminoglycoside Antibacterial

ATC Vet Code: QJ01GA01

5.1 Pharmacodynamic properties

Streptomycin is a member of the amino glycosides 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

Chlorocresol
Sodium Metabisulphite
Sodium Citrate (for pH adjustment)
Citric acid, Anhydrous
Water for injections.

6.2 Incompatibilities

None Known.

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 ºC
Protect from light.
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material.

6.5 Nature and composition of immediate packaging

Amber Type II glass vials siliconised, multidose of 50 ml and 100 ml closed with aluminium cap unlacquered, nitryl rubber bungs.
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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4018

9. DATE OF FIRST AUTHORISATION

24 October 2005

10. DATE OF REVISION OF THE TEXT

December 2015

17 December 2015