SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Devomycin D Solution for Injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Each ml contains:
Streptomycin Sulfate 150 mg
Dihydrostreptomycin Sulfate 150 mg.

Excipients:
Chlorocresol 1mg
Sodium Metabisulphate 1mg

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for Injection
A clear pale yellow solution for Injection.

4. CLINICAL PARTICULARS

4.1 Target species

Horses
Cattle
Sheep
Dogs
Cats

4.2 Indications for use, specifying the target species

Devomycin D Injection is active against a wide range of Gram-negative organisms and some Gram-positive pathogens. It is indicated in the treatment of organisms sensitive to Streptomycin. Among the more sensitive to streptomycin *in vitro* are *Actinobacillus equuli*, *A. lignieresii*, *Actinomyces bovis*, *Brucella* spp, *E. coli*, *Haemophilus* spp, *Klebsiella* spp, *Leptospira canicola* and *L. ictero-haemorrhagiae, Pseudomonas aeruginosa* and some species of *Proteus*, *Pasteurella* and *Salmonella*.

4.3 Contraindications

Contraindicated 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

i. Special precautions for use in animals

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.

Take particular care when treating animals suffering from renal damage.

ii. 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 D 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

For intramuscular injection only.

Horses, cattle and sheep: 10 mg active ingredients/kg bodyweight daily (1 ml/30 kg bodyweight) for a maximum of 3 days.
Dogs and cats: 25 mg active ingredients/kg bodyweight daily (1 ml/12 kg bodyweight) for a maximum of 3 days.

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

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

Do not inject more than 10ml of this product into any one injection site. Failure to heed this warning may lead to residues above the legal limit in food for human consumption.

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 & Offal): 14 days
Cattle (Milk): 48 hours

Sheep (Meat & Offal): 14 days
Sheep (Milk): Do not use in sheep producing milk intended for human consumption.

Horses: Not to be used in horse 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: Antibacterials for systemic use, Aminoglycoside antibacterials, Streptomycins

ATC Vet Codes: QJ01GA01 & QJ01GA90

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 Metabisulphate
Sodium Citrate Anhydrous
Citric acid, Anhydrous (for pH adjustment)
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 25ºC.
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

100ml sterile, amber, type II glass siliconised, multi-dose vials closed with grey rubber plug septum secured by a aluminium tamper evident crimped seal.

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

Any unused product or waste material 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

Vm 02000/4034

9. DATE OF RENEWAL OF AUTHORISATION

Date: 24 October 2010

10. DATE OF REVISION OF THE TEXT

Date: April 2011