Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphar Streptomycin

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance

Streptomycin (as Streptomycin Sulphate)	200,000 Units

Excipients

Chlorocresol	1 mg
Sodium metabisulphite (E223)	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 and Pigs

4.2 Indications for use, specifying the target species

Duphar Streptomycin 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

Contraindicated in cases of known hypersensitivity to the active ingredients. 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.
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

Duphar Streptomycin 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 (1 ml / 20 kg) is recommended for up to three days.

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

Excessive and prolonged administration of streptomycin may cause renal damage and 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)

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 Injections

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 100 ml, sealed with nitryl rubber bungs and aluminium unlacquered caps.

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

Zoetis Ireland Limited
25/28 North Wall Quay
Dublin 1
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10438/040/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT

August 2013