

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphacycline 10% Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Oxytetracycline Hydrochloride	100	mg/ml
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Excipients:

Sodium Formaldehyde Sulfoxylate	1.5	mg/ml
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For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.

A clear yellow aqueous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, Sheep and Pigs

4.2 Indications for use, specifying the target species

Duphacycline 10 % is indicated in the treatment of a wide range of common systemic, respiratory and local infections caused by or associated with organisms sensitive to Oxytetracycline in cattle, sheep and pigs.

4.3 Contraindications

Do not use in animals suffering from renal or hepatic damage.

Do not use in animals with known hypersensitivity to Oxytetracycline.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

If the volume of product to be administered is greater than 20 ml it should be divided and injected into two sites.

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

None

4.6 Adverse reactions (frequency and seriousness)

No known undesirable effects.

4.7 Use during pregnancy, lactation or lay

The use of tetracycline during the period of tooth development, including late pregnancy may lead to tooth discoloration. Duphacycline 10% can be safely administered during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Dilution with solutions of Calcium salts will cause precipitation and must be avoided.

4.9 Amounts to be administered and administration route

Administer by intramuscular injection or slow intravenous injection in cattle and by intramuscular injection in pigs and sheep. The recommended dosage is as follows:

Cattle: 4 mg/kg (2 ml per 50 kg bodyweight), daily for three to five days.

Sheep: 4 - 9 mg/kg (2 - 4.5 ml per 50 kg bodyweight), daily for three to five days.

Pigs: 4 - 9 mg/kg (2 - 4.5 ml per 50 kg bodyweight), daily for three to five days.

It is recommended that when the intravenous route is used in cattle, no more than two consecutive daily injections are administered.

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

Not applicable.

4.11 Withdrawal Period(s)

Cattle:

Meat and offal: 18 days

Milk: 84 hours

Pigs:

Meat and offal: 15 days

Sheep:

Meat and offal: 15 days

Do not use in sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinfectante for systemic use; Oxytetracycline.

ATCvet code: QJ01AA06

5.1 Pharmacodynamic properties

Oxytetracycline is a bacteriostatic antibiotic that inhibits protein synthesis in susceptible bacteria. Inside the cell it binds irreversibly to receptors on the 30S subunit of the bacterial ribosome where it interferes with the binding of the amino-acyl transfer RNA to the receptor site on the messenger RNA Ribosome complex. This effectively prevents the addition of the amino acids to the elongating peptide chain, inhibiting protein synthesis.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Chloride
Dimethylacetamide
Ethanolamine
Citric Acid
Sodium Formaldehyde Sulfoxylate
Water for Injections

6.2 Incompatibilities

Dilution with solutions of calcium salts will cause precipitation and must be avoided.

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°C.

6.5 Nature and composition of immediate packaging

Amber Type II 100ml glass vials sealed with a nitrile rubber stopper and aluminium overseal.

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
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10438/027/002

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT

August 2013