Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphacycline LA Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance

Oxytetracycline (as Oxytetracycline Dihydrate)	200	mg

Excipient

Sodium Formaldehyde Sulphoxylate	4	mg

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 LA 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 hepatic or renal 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 precaution(s) for use in animals

Do not dilute Duphacycline LA.
If concurrent treatment is administered use a separate injection site.

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

Wash hands after use. In case of contact with eyes or skin, wash immediately with water as irritation may occur.

4.6 Adverse reactions (frequency and seriousness)

Although Duphacycline LA is well tolerated occasionally a slight local reaction of a transient nature has been observed.

4.7 Use during pregnancy, lactation or lay

The use of tetracycline during the period of tooth and bone development, including late pregnancy may lead to tooth discoloration. Duphacycline LA can be safely administered to lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

The recommended dose rate is 20 mg/kg bodyweight (ie. 1ml per 10 kg bodyweight) administered by deep intramuscular injection. The product is recommended for a single administration only.

Maximum recommended dose at any one site:

Cattle:	20 ml
Pigs:	10 ml
Sheep:	5 ml
Piglets:	
1 day	0.2 ml
7 days	0.3 ml
14 days	0.4 ml
21 days	0.5 ml
over 21 days	1.0 ml/10kg

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

Not applicable.

4.11 Withdrawal Period(s)

Cattle:
Meat and offal: 28 days
Milk: 7 days

Pigs:
Meat and offal: 14 days

Sheep:
Meat and offal: 7 days
Milk: 6 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use; tetracyclines.
ATCvet code: QJ01AA06

5.1 Pharmacodynamic properties

Oxytetracycline is a bacteriostic 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. Duphacycline LA is specifically formulated to provide a prolonged action resulting in sustained antibacterial activity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Oxide
Dimethylacetamide
Disodium Edetate
Ethanolamine
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 glass vials of 100 ml with bromobutyl rubber bungs and aluminium overseals.

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 10438/029/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30 September 2008

10 DATE OF REVISION OF THE TEXT

April 2012
August 2013