SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphacycline LA 20% Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances:	Per ml
Oxytetracycline	200mg
(equivalent to 216mg Oxytetracycline dehydrate per ml)	

Excipients:
Sodium Formaldehyde Sulphoxylate (antioxidant) 4mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
A clear amber liquid, free from visible particles

4. CLINICAL PARTICULARS

4.1 Target Species

Cattle, sheep and pigs.

4.2 Indications for use specifying the target species

Oxytetracycline is active against a wide range of Gram-positive and Gram-negative pathogenic bacteria and certain rickettsia. The product is indicated for 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. These include: *Bordetella bronchiseptica*, *Actinomyces pyogenes*, *Erysipelothrix rhusiopathiae*, *Escherichia coli*, *Haemophilus somnus*, *Mannheimia haemolytica*, *Pasteurella multocida*, *Salmonella dublin*, *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus faecalis*, *Streptococcus pyogenes* and *Streptococcus uberis*.

4.3 Contraindications

Not recommended for use in horses, dogs or cats. Contraindicated in animals suffering from hepatic or renal damage and in animals with known hypersensitivity to Oxytetracycline.

4.4 Special warnings

None

4.5 Special precautions for use

i) Special precautions for use in animals
Do not dilute. If concurrent treatment is administered use a separate injection site.

ii) 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 well tolerated occasionally a slight local reaction of a transient nature may be observed.

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. The product can be safely administered during lactation.

4.8 Interactions with other medicinal products and other forms of interaction

It is not recommended to administer bacteriostatic and bactericidal antimicrobials concurrently.

4.9 Amounts to be administered and administration route

The recommended dose rate is 20mg/kg bodyweight (ie 1ml per 10kg bodyweight) administered by deep intramuscular injection.
Maximum recommended dose at any one site:

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

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

Not applicable.

4.11 Withdrawal periods

Cattle
Meat – 31 days
Milk – 10 days
Sheep
Meat – 9 days
Milk – 7 days
Pigs
Meat – 18 days

5. PHARMACOLOGICAL 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-actyl transfer RNA to the acceptor site on the messenger RNA ribosome complex. This effectively prevents the addition of the amino acids to the elongating peptide chain, inhibiting protein synthesis. Following intramuscular injection, peak blood levels are achieved within 4-8 hours and persist for at least four days. The product is specifically formulated to provide a prolonged action resulting in sustained antibacterial activity.
ATC vet code: QD06AA03

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Formaldehyde Sulphoxylate
Magnesium Oxide Light
Dimethylacetamide
Sulphoxylate Dihydrate
Disodium Edetate Dihydtrate
Ethanolamine
Water for injections

6.2 Incompatibilities

Refer to section 4.8

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
Shelf-life after withdrawal of the first dose: 28 days
Discard unused material safely

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.
When the vial has been broached and contents exposed to air, solution may darken, but the potency will be unchanged.

6.5 Nature and composition of immediate packaging

Amber Type I or II glass vials of 50ml and 100ml with bromobutyl bung.

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

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

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
5th Floor, 6 St. Andrew Street
London
EC4A 3AE

8. MARKETING AUTHORISATION NUMBERS

Vm 42058/4039

9. DATE OF RENEWAL OF THE AUTHORISATION

Date: 07 April 2009

10. DATE OF REVISION OF THE TEXT

Date: April 2014

03 April 2014