SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Oxytetrin 20 LA 200 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	mg/ml
Oxytetracycline (as Oxytetracycline Dihydrate)	200
Excipients	
Polyvinylpyrrolidone (K – 17)	25
N-Methyl Pyrrolidone	370

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.
A clear sterile, yellow to amber aqueous solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, sheep and pigs

4.2 Indications for use, specifying the target species

For the treatment and control of diseases caused by or associated with organisms sensitive to Oxytetracycline in cattle, sheep and pigs.

4.3 Contra-indications

Not recommended for use in cats, dogs, horses and donkeys.
Do not use in animals producing milk for human consumption.

4.4 Special warnings for each target species

Prolonged use of anti-infectives may result in superinfection by non-susceptible organisms. Photodermatitis may be observed after treatment with oxytetracycline.

4.5 Special precautions for use

i. Special precautions for use in animals

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.

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

Wash hands after use. Avoid contact with eyes.

4.6 Adverse reactions (frequency and seriousness)

Occasional local reaction of a transient nature may occur at the site of injection.

4.7 Use during pregnancy and lactation

The use of Oxytetrin 20 LA during the period of tooth development including late pregnancy, may lead to tooth discolouration.

4.8 Interaction with other medicinal products and other forms of interactions

Not to be diluted with solutions of calcium salts as this causes precipitation.

4.9 Amounts to be administered and administration route

Administer by deep intramuscular injection at the rate of 1 ml per 10 kg bodyweight which is equivalent to 20 mg Oxytetracycline per kg.

It is recommended that the following volumes at one site should not be exceeded:

Cattle and Sheep	-	10ml
Pigs	-	5ml

Pigs under 10 kg maximum dose of 1ml

Effective blood levels are maintained for up to 72 hours in cattle and 48 hours in pigs and sheep.

Because of the sustained blood levels attained at the above dosage rates, one treatment is usually sufficient.

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

No treatment specified.

4.11 Withdrawal Period(s)

Meat withdrawal time:

Cattle (meat and offal):	39 days from the last treatment.
Pigs (meat and offal):	40 days from the last treatment.
Sheep (meat and offal):	28 days from the last treatment.

This product is not for use in animals producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, oxytetracyline

ACT Vet code: QJ01AA06

5.1 Pharmacodynamic properties

The product is a multidose injection formulation containing Oxytetracycline Dihydrate equivalent to 200 mg Oxytetracycline per ml as a magnesium complex.

Oxytetracycline is a broad spectrum antibiotic of the tetracycline group. It is derived from a soil mould, *Actinomyces rimosus.* Oxytetracycline is bacteriostatic at therapeutic concentration but may be bactericidal at higher concentrations.

The mode of action of Oxytetracycline and other tetracyclines involves interference with protein and RNA synthesis in the growing and reproducing bacterial cell.

The product is long acting and is intended to be administered as a single dose which will maintain therapeutic blood levels for up to three days. Long acting antibiotic preparations are not only convenient but may also provide more constant blood and tissue drug concentrations by avoiding the peaks and troughs associated with conventional administration. Another important advantage is avoidance of the stress and irritation to the animals of repeated injection.

The product is recommended for the treatment and control of diseases in cattle, sheep and pigs caused by or associated with organisms sensitive to Oxytetracycline.

5.2 Pharmacokinetic particulars

Not known.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Oxide Heavy
N-Methyl Pyrrolidone
Pvidone (Polyvinylpyrrolidone) K-17
Sodium formaldehyde sulphoxylate (as Sodium formaldehyde sulphoxylate dihydrate)
Ethanolamine (for pH adjustment)
Hydrochloric Acid (for pH adjustment)
Water for Injection

6.2 Incompatibilities

The product should not be brought into contact with calcium solutions.
Do not dilute.

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. Protect from light. The product should be discarded 28 days after withdrawal of the first dose.

6.5 Nature and composition of immediate packaging

100 ml amber Type II glass vials, fitted with bromobutyl rubber stoppers and sealed with plain aluminum caps.

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

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

Intervet UK Ltd
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4563

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01/06/1995

10. DATE OF REVISION OF THE TEXT

Date: April 2012