Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Aquacycline 10% Solution for Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:	
Active Substance	
Oxytetracycline Hydrochloride	100 mg
Excipients	
Methyl Parahydroxybenzoate (E218).	1.25 mg
Sodium Formaldehyde Sulfoxylate	5.00 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, pigs and sheep.

4.2 Indications for use, specifying the target species

For the treatment of infections caused by microorganisms sensitive to oxytetracycline, including:
Salmonella spp.
Pasteurella spp.
Haemophilus somnus
Corynebacterium pyogenes
Bordetella bronchiseptica

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

Transient discomfort may be observed in sheep following intramuscular administration. Slow intravenous administration (over 3 minutes) to cattle is recommended.

4.5 Special precautions for use

Special precautions for use in animals

Please refer to item 5.3 and 5.8.

Special Precautions to be taken by the Person Administering the Product to Animals

None.

4.6 Adverse reactions (frequency and seriousness)

Circulatory collapse may occur in case of rapid intravenous administration. Transient discomfort may be observed in sheep following intramuscular administration.

4.7 Use during pregnancy, lactation or lay

This product may be used 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

Recommended dose: 5-10 mg oxytetracycline/kg bodyweight (equivalent to 0.5 - 1 ml per 10 kg bodyweight) once a day. AQUACYCLINE™-10 is suitable for intramuscular administration to cattle, pigs and sheep, and for slow intravenous administration (over 3 minutes) to cattle. Where large dose volumes are to be injected intramuscularly, it is recommended to divide the dose and inject at two separate sites.
With highly sensitive organisms the dose can be repeated at 36 hour intervals, but less sensitive infections require 12 hour dose intervals.
The treatment may be repeated for 2 - 3 days, depending on the dose interval and severity of the disease.

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

Avoid overdose for animals with liver and kidney insufficiency.

4.11 Withdrawal Period(s)

After intravenous administration in cattle:

Milk for human consumption must not be taken from a cow during treatment. With cows milked twice daily milk for human consumption may only be taken after 4 days from the last treatment.

Animals intended for human consumption should not be slaughtered until after 10 days after the last treatment.

After intramuscular administration in pigs, cattle and sheep:

Milk for human consumption must not be taken from a cow during treatment. With cows and sheep milked twice daily milk for human consumption may only be taken after 6 days from the last treatment.

Animals intended for human consumption should not be slaughtered until after 30 days after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Oxytetracycline is a bacteriostatic antibiotic belonging to the tetracycline group, which acts by inhibition of the protein synthesis. The antimicrobial spectrum of oxytetracycline includes a broad range of both aerobic and anaerobic Gram-positive and Gram-negative bacteria, Chlamydia, Rickettsiae, and some Mycoplasmas.

Absorption from injection site is good and rapid. Effective therapeutic blood levels are produced 30 minutes after intramuscular injection. Levels in excess of 0.5 µg/ml are maintained for more than 24 hours following intramuscular administration at 10 mg/kg.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate (E218)
Magnesium Oxide, Heavy
Monoethanolamine
Sodium Formaldehyde Sulfoxylate
Povidone K-17
Propylene Glycol
Water for Injections

6.2 Incompatibilities

Avoid dilution with liquids containing calcium salts.

6.3 Shelf-life

Two years if the vial has not been opened.
Following withdrawal of the first dose, use the product within 28 days.

6.4 Special precautions for storage

Protect from light. Store at 2-8°C.

6.5 Nature and composition of immediate packaging

Amber vial, 100ml, Type I glass with bromobutyl stoppers and metal 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

Ceva Animal Health Limited
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10995/022/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2003

10 DATE OF REVISION OF THE TEXT

10th November 2011