SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Terramycin Soluble Powder Concentrated 20% w/w Oral Powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:

Oxytetracycline	20 % w/w (200 g/kg)
(equivalent to Oxytetracycline hydrochloride*	22 % w/w

*based on a potency of 910 mcg oxytetracycline base per 1 mg

For a full list of excipients, see Section 6.1

3. PHARMACEUTICAL FORM

Oral Powder
Pale yellow to dark yellow free flowing powder.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (over 160 kg bodyweight).
Calves.
Pigs.

4.2 Indications for use, specifying the target species

Cattle (over 160 kg bodyweight): Respiratory disease.
Calves: Bacterial enteritis.
Pigs: Respiratory disease.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Acutely ill animals are unlikely to consume an adequate dose unless treated by drinking water or drench methods.

When given via the drinking water remove all other sources of water until the medicated water has been consumed.

Following oral dosage in ruminants, changes in the ruminal flora may occur but these have generally been found to be of a transitory and reversible nature. Administration of Terramycin at the recommended dosage will usually result in only a small depression of cellulose digestion.

Bacterial resistance may develop after long term use of oxytetracycline. This is particularly likely in enterobacteria and *Salmonella*, many of which are already resistant.

Salmonella shedding in treated animals will continue where organisms are resistant.

4.5 Special precautions for use

i. Special precautions for use in animals

None.

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

If you know you are hypersensitive (allergic) to oxytetracycline, do not handle the product.

When handling the product avoid inhalation of dust by wearing a disposable half-mask respirator conforming to European Standards EN 149 (FFP2) or a non-disposable respirator to European Standards EN 140 with a filter to EN 143.

Wear gloves and avoid contact with skin and eyes. In case of contact, wash area immediately with fresh water. If irritation persists seek medical attention. Hands and exposed skin should be washed thoroughly after use.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during pregnancy, lactation or lay

No adverse effects.

4.8 Interaction with other medicinal products and other forms of interaction

Interactions may occur with solutions with high calcium, magnesium or sodium content.

4.9 Amounts to be administered and administration route

For oral administration in the drinking water or as a drench.

Each pack is supplied with a measure dispensing 1000 mg (1 gram) oxytetracycline hydrochloride when filled level. Treatment period 3-5 days.

Calf: 9-18 mg/kg/day oxytetracycline hydrochloride (½-1 measure per 110 kg bodyweight) twice daily.

Ruminating cattle: 2-4 mg/kg/day oxytetracycline hydrochloride (½-1 measure per 500 kg. bodyweight) twice daily

Pigs: 10-30 mg/kg/day oxytetracycline hydrochloride (½-1½ measure per 50 kg bodyweight).
4-12.5 g oxytetracycline hydrochloride per 10 gallons. 1 x 250 g pack medicates 124 gallons of drinking water at the lower dosage level.

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

The safety margin of oxytetracycline in the target species is very wide and toxic signs are unlikely to be seen. Large overdoses are potentially nephrotoxic

4.11 Withdrawal period(s)

Cattle: Meat - 10 days
Milk: zero hours. Milk may not be taken for human consumption during treatment.
Pigs: 7 days

5. PHARMACOLOGICAL PROPERTIES

Oxytetracycline is a member of the tetracycline group of antibiotics and is produced by fermentation of *Streptomyces rimosus*.

It possesses broad spectrum antimicrobial activity against a wide range of gram +ve and gram -ve bacteria, certain *Mycoplasma* spp, protozoa and rickettsiae.

Oxytetracycline is bacteriostatic in action and acts by inhibiting protein synthesis in the bacterial cell.

When given by mouth in solution oxytetracycline acts locally in the gut and is absorbed into the bloodstream and distributed to the tissues especially lung tissue.

Blood and tissue levels are measurable with the sensitive HPLC assay.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate
Tartaric Acid

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf-life after dilution or reconstitution according to directions: 24 hours.

6.4 Special precautions for storage

Store in a dry place. Do not store above 25°C.
Any medicated water remaining after 24 hours should be discarded.

6.5 Nature and composition of immediate packaging

Securitainers, white opaque polypropylene body with white opaque tamper-proof cap with tear tab and score lines containing 250 g (9oz approx).
White high density polyethylene body (HDPE) with a low density polyethylene (LDPE) tamper-proof cap.

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
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

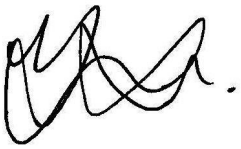
Vm 42058/4204

9. DATE OF THE FIRST AUTHORISATION

1 December 1988

10. DATE OF REVISION OF THE TEXT

August 2020



Approved: 27 August 2020