

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Terramycin Soluble Powder Concentrated 20% w/w Oral Powder

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

This pack contains 200 g per kg (20% w/w) Oxytetracycline (equivalent to Oxytetracycline hydrochloride 22% w/w)

3. PHARMACEUTICAL FORM

Oral powder

4. PACKAGE SIZE

250 g

5. TARGET SPECIES

Cattle (ruminating).

Calves.

Pigs.

6. INDICATION(S)

Recommended for oral administration to cattle and pigs for the treatment of a range of bacterial infections caused by, or associated with, oxytetracycline sensitive organisms.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Calves: ½-1 measure per 110 kg bodyweight twice daily. ie 9-18 mg oxytetracycline hydrochloride per kg bodyweight per day.

Cattle (ruminating): ½-1 measure per 500 kg bodyweight twice daily. ie 2-4 mg oxytetracycline hydrochloride per kg bodyweight per day.

Pigs: (½-1½ measures per 50 kg bodyweight daily. ie 10-30 mg oxytetracycline hydrochloride per kg daily.

4-12.5g oxytetracycline hydrochloride per 10 gallons of water. ie 1 x 250 g pack medicates 124 gallons of water at the lower dosage level..

3-5 days treatment is usually sufficient.. When given via drinking water remove all other sources of water until the medicated water has been consumed.

One level measure (measure supplied) contains 1000 mg (1 g) oxytetracycline (Approx. 50 level measures in a 250 g pack).

8. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment.

Cattle (meat): 10 days.

Pigs (meat): 7 days.

Cattle (milk): Zero hours.

Milk may not be taken for human consumption during treatment.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

Following oral dosage in ruminating animals changes in the ruminal flora which may occur have generally been transitory and reversible. At recommended dosage Terramycin will usually result in only a small depression of cellulose digestion.

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

10. EXPIRY DATE

Expires end:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Any medicated water which is not consumed within 24 hours should be discarded

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]

POM-V

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4204

17. MANUFACTURER'S BATCH NUMBER

Lot:

PACKAGE LEAFLET FOR: Terramycin Soluble Powder Concentrated 20% w/w
Oral Powder

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Terramycin Soluble Powder Concentrated 20% w/w Oral Powder

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Terramycin Soluble Powder Concentrated 20% w/w Oral Powder is a pale yellow/dark yellow, free flowing powder containing 200 g per kg (20% w/w) Oxytetracycline (equivalent to Oxytetracycline hydrochloride 22 % w/w) in a water soluble base.

4. INDICATION(S)

Terramycin is indicated for the treatment of a range of bacterial infection caused by, or associated with, oxytetracycline sensitive organisms. A wide range of Gram-positive and Gram-negative bacteria, certain mycoplasma species and rickettsiae, have been shown to be sensitive *in vitro* to oxytetracycline.

Terramycin Soluble Powder 20% is recommended for oral medication of cattle and pigs.

Cattle (over 160 kg bodyweight): Respiratory disease.

Calf: Bacterial enteritis.

Pigs: Respiratory disease.

5. CONTRAINDICATIONS

6. ADVERSE REACTIONS

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

7. TARGET SPECIES

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Terramycin Soluble Powder 20% is recommended for oral administration and may be given in the drinking water or as a drench.

A period of treatment for 3-5 days is usually sufficient.

To reconstitute the powder it should be agitated vigorously in a small volume of water and added to the bulk tank when fully dissolved.

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

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

Pigs: ½-1½ level measure per 50 kg bodyweight daily (10-30 mg oxytetracycline hydrochloride per kg per day).

4-12.5 g oxytetracycline hydrochloride per 45 litres (10 gallons) of drinking water ie. 1 x 250 g pack medicates 567 litres (124 gallons) at the lower dosage level.

Each pack is supplied with a measure(s). One level measure of Terramycin Soluble Powder 20% contains approximately 1000 mg oxytetracycline hydrochloride.

9. ADVICE ON CORRECT ADMINISTRATION

Any medicated feed not consumed within 24 hours should be discarded.

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

10. WITHDRAWAL PERIOD(S)

Animals must not be slaughtered for human consumption during treatment.

Cattle (meat): 10 days

Pigs (meat): 7 days

Cattle (milk): Zero hours.

Milk may not be taken for human consumption during treatment.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of reach of children. Store in a dry place. Do not store above 25°C.

12. SPECIAL WARNING(S)

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.

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

Following oral dosage in ruminating animals 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.

For animal treatment only

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

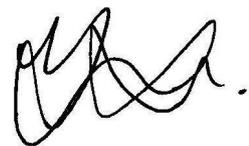
August 2020

15. OTHER INFORMATION

POM-V To be supplied only on veterinary prescription

Vm 42058/4204

Package quantities: 250 g securitainer



Approved: 27 August 2020