

## **PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Bottle label}**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Terramycin/LA 200 mg/ml Solution for Injection

### **2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each ml contains:

200 mg Oxytetracycline (as dihydrate) and 2.20 mg sodium formaldehyde sulfoxylate as preservative.

### **3. PHARMACEUTICAL FORM**

Solution for Injection

### **4. PACKAGE SIZE**

100 ml

### **5. TARGET SPECIES**

Cattle, pigs and sheep

### **6. INDICATION(S)**

For the treatment and control of conditions caused by, or associated with, organisms susceptible to the action of oxytetracycline.

### **7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Intramuscular injection (for long acting effect).

Dosage 1ml/10 kg.

Recommended for deep intramuscular injection to cattle, pigs and sheep.

See package leaflet for full dosing instructions.

|   |                             |   |                               |   |                                |   |                               |
|---|-----------------------------|---|-------------------------------|---|--------------------------------|---|-------------------------------|
|  | <b>PIG</b><br>50 kg<br>5 ml |  | <b>SHEEP</b><br>50 kg<br>5 ml |  | <b>CALF</b><br>100 kg<br>10 ml |  | <b>COW</b><br>400 kg<br>40 ml |
|---|-----------------------------|---|-------------------------------|---|--------------------------------|---|-------------------------------|

### **8. WITHDRAWAL PERIOD**

Cattle: Meat – 36 days, Milk – 7 days

Pigs: Meat – 36 days

Sheep: Meat – 24 days

Not for use in ewes producing milk for human consumption.

## **9. SPECIAL WARNING(S), IF NECESSARY**

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## **10. EXPIRY DATE**

EXP:

## **11. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C.

Following withdrawal of the first dose, use the product within 28 days.

The formulation will freeze at -2°C but, on thawing, reverts completely to its original condition.

Date of broaching:

Date of discard:

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

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

## **13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE**

For animal treatment only.

POM-V

To be supplied only on veterinary prescription.

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

Keep out of the sight and 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 42058/4151

**17. MANUFACTURER'S BATCH NUMBER**

Lot:

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Folding carton}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Terramycin/LA 200 mg/ml Solution for Injection

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each ml contains:

200 mg Oxytetracycline (as dihydrate) and 2.20 mg sodium formaldehyde sulfoxylate as preservative.

**3. PHARMACEUTICAL FORM**

Solution for Injection

**4. PACKAGE SIZE**

100 ml

**5. TARGET SPECIES**

Cattle, pigs and sheep

**6. INDICATION(S)**

-

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Intramuscular injection (for long acting effect).

Dosage 1ml/10 kg.

Recommended for deep intramuscular injection to cattle, pigs and sheep.

See package leaflet for full dosing instructions.

For further information see package leaflet.

**8. WITHDRAWAL PERIOD**

Cattle: Meat – 36 days, Milk – 7 days

Pigs: Meat – 36 days

Sheep: Meat – 24 days

Not for use in ewes producing milk for human consumption.

**9. SPECIAL WARNING(S), IF NECESSARY**

Not recommended for cats, dogs or horses.

## **10. EXPIRY DATE**

EXP:

## **11. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C. The formulation will freeze at -2°C but, on thawing, reverts completely to its original condition.

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

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

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

## **13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE**

For animal treatment only.

**POM-V**

To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

## **15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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1st Floor, Birchwood Building  
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## **16. MARKETING AUTHORISATION NUMBER(S)**

Vm 42058/4151

## **17. MANUFACTURER’S BATCH NUMBER**

Lot:

**PACKAGE LEAFLET FOR:**

Terramycin/LA 200 mg/ml Solution for Injection

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

**MA Holder:**

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

**Manufacturer responsible for batch release:**

Zoetis Manufacturing & Research Spain S.L.  
Ctra. Camprodon s/n "La Riba"  
17813 Vall de Bianya  
Girona  
Spain

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Terramycin/LA 200 mg/ml Solution for Injection

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

Each ml contains:

**Active substance:**

Oxytetracycline (as dihydrate) .....200 mg

**Excipient:**

Sodium Formaldehyde Sulfoxylate.....2.20 mg

Light to dark yellowish brown solution for injection. It may have a green tint.

**4. INDICATION(S)**

TERRAMYCIN/LA Solution for Injection is a solution of oxytetracycline specially formulated to give long acting effect when given by intramuscular injection.

Terramycin is a broad spectrum antibiotic, and is indicated for the treatment and control of conditions caused by, or associated with, oxytetracycline-sensitive organisms. A large number of Gram-positive and Gram-negative bacteria, certain

mycoplasma species, rickettsiae, protozoa and the chlamydiae are sensitive to oxytetracycline.

**CATTLE:** For the treatment and control of pasteurellosis and pneumonia caused by oxytetracycline-sensitive organisms. The product may also be of value for foul-in-the-foot.

**PIGS:** For the treatment of pneumonia caused by *Pasteurella*.

**SHEEP:** For the control of enzootic abortion and pneumonia caused by oxytetracycline sensitive organisms. The product may aid in the treatment of footrot, acute severe mastitis, infectious ovine keratoconjunctivitis (pink-eye).

## **5. CONTRAINDICATIONS**

Not recommended for cats, dogs or horses.

Not to be injected subcutaneously except in piglets under 10 kg bodyweight.

Use with caution in animals with hepatic or renal impairment.

Concomitant vaccination is not recommended.

Do not combine with bactericidal antimicrobial products or with infusion fluids.

Bacterial resistance may exist or develop after prolonged use of tetracyclines.

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

Do not dilute.

## **6. ADVERSE REACTIONS**

Local reactions at the injection site may occur.

In very rare cases, hypersensitivity, allergic or anaphylactic type reactions may occur. In case of a serious anaphylactic reaction the administration of appropriate treatment (epinephrine, adrenaline, steroids, antihistamines, Ca) is recommended.

TERRAMYCIN/LA Solution for Injection is generally well tolerated. Occasional reactions following injection are of a transient nature.

## **7. TARGET SPECIES**

Cattle, pigs and sheep

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

For long acting effect, the dosage rate for cattle, pigs and sheep is 20 mg/kg bodyweight (i.e. 1 ml TERRAMYCIN/LA Solution for Injection per 10 kg bodyweight once). It is recommended in cattle that not more than 10 ml, and in sheep and pigs not more than 5 ml be injected at any one site.

## **9. ADVICE ON CORRECT ADMINISTRATION**

For long acting effect, TERRAMYCIN/LA Solution for Injection is recommended for administration by deep intramuscular injection.

In pigs weighing less than 10 kg a 1 ml dose should be used.

If concurrent treatment is administered use a separate injection site.

## **10. WITHDRAWAL PERIOD(S)**

**Cattle:** Meat – 36 days, Milk – 7 days  
**Pigs:** Meat – 36 days  
**Sheep:** Meat – 24 days

Not for use in ewes producing milk for human consumption.

## **11. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25°C. The formulation will freeze at -2°C but, on thawing, reverts completely to its original condition.

Following withdrawal of the first dose, use the product within 28 days. Discard unused material. Contamination of broached vials during use should be avoided.

When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided on the label.

## **12. SPECIAL WARNING(S)**

Resistance against oxytetracycline may vary.

Use of the product should be based on susceptibility testing of 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.

Inappropriate use of the product may increase the prevalence of bacteria resistant to oxytetracycline and may decrease the effectiveness of treatment with tetracyclines due to the potential for cross resistance.



Oxytetracycline may interfere with the action of bactericidal antimicrobials, such as penicillins and cephalosporins, and therefore they should not be used simultaneously.

Operator warnings:

This product may cause hypersensitivity reactions (allergy). Persons with a known hypersensitivity to tetracyclines should not handle this product.

Wash hands after use.

In case of contact with eyes or skin, wash off immediately with water as irritation may occur. Avoid accidental self-injection.

Keep out of the sight and reach of children.

For animal treatment only.

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

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

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

November 2022

**15. OTHER INFORMATION**

POM-V

To be supplied only on veterinary prescription.

Vm 42058/4151

Multi-dose vials of 100 ml.

The preparation may darken on exposure to air but the potency of the Terramycin remains unchanged.

**Notes:**

TERRAMYCIN/LA Solution for Injection is specially formulated to provide persistent blood levels following an intramuscular dose of 20 mg/kg bodyweight. In the majority of animals treated with TERRAMYCIN/LA Solution for Injection, antibiotic cover will persist for at least 4 days.

In addition, TERRAMYCIN/LA Solution for Injection at 20 mg/kg bodyweight in cattle, pigs and sheep will provide high antibacterial blood levels within thirty minutes after injection and for up to 12 hours.

TERRAMYCIN/LA Solution for Injection is therefore suitable for therapy of acute infections.

Approved 15 November 2022

A handwritten signature in black ink, consisting of a stylized initial 'M' followed by the name 'Hunter.' with a period.