PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label Text

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TETROXY LA
200mg/ml Oxytetracycline Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

CONCENTRATION: Each ml contains: Oxytetracycline dihydrate Ph Eur equivalent to 200mg Oxytetracycline base, as the magnesium complex. Contains Povidone and NMP as co-solvents.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

100ml

5. TARGET SPECIES

Pigs, Cattle, Sheep

6. INDICATION(S)

INDICATIONS FOR USE: Tetroxy LA is indicated in the treatment and control of diseases caused by or associated with organisms sensitive to oxytetracycline in cattle, sheep and pigs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

DOSAGE AND ADMINISTRATION: Tetroxy LA is administered by deep intramuscular injection at the rate of 1 ml per 10 kg bodyweight which is equivalent to 20 mg oxytetracycline per kg.

The following amounts of Tetroxy LA at one site should not be exceeded:
Cattle, Sheep: 10 ml Pigs: 5ml
Pigs under 10 kg maximum dose of 1 ml.
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 this is a single dose treatment.

8. WITHDRAWAL PERIOD

WITHDRAWAL PERIODS:
Cattle (meat & offal): 39 days.
Pigs (meat & offal): 40 days
Sheep (meat & offal): 28 days
Do not use in animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

CONTRAINDICATIONS AND WARNINGS: Not recommended for cats, dogs, horses and donkeys.
The use of Tetroxy LA during the period of tooth development including late pregnancy may lead to tooth discolouration.

Read carton for user warnings.

10. EXPIRY DATE

Expiry Date:

11. SPECIAL STORAGE CONDITIONS

PROTECT FROM LIGHT
DO NOT STORE ABOVE 25°C.
DO NOT DILUTE
PHARMACEUTICAL WARNINGS: Following withdrawal of the first dose, use the product within 28 days.
Once broached, discard by / /

Keep the container in the outer carton.

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

Disposal: 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

FOR ANIMAL TREATMENT ONLY
To be supplied only on veterinary prescription. POM- V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF REACH AND SIGHT OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4028

17. MANUFACTURER'S BATCH NUMBER

Batch No:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Container Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TETROXY LA
200mg/ml oxytetracycline solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 200 mg Oxytetracycline (as Oxytetracycline dihydrate Ph Eur). Also contains Povidone and N methyl pyrrolidone as co-solvents and Sodium formaldehyde sulfoxylate 0.5% as an antioxidant. This product does not contain an antimicrobial preservative.

3. PHARMACEUTICAL FORM

A long acting oxytetracycline solution for injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, Sheep and Pigs

6. INDICATION(S)

Not stated on carton.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For use in cattle, sheep and pigs by intramuscular injection and dogs by subcutaneous injection.

8. WITHDRAWAL PERIOD

Withdrawal periods: Cattle (meat & offal): 39 days
Pigs (meat & offal): 40 days
Sheep (meat & offal): 28 days
Do not use in animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

User Warnings:
Take care to avoid self injection. In case of contact with eyes or skin, wash immediately with plenty of water as irritation may occur. Wash hands after use.

Further information – see label

10. EXPIRY DATE

Expiry Date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C
Protect from light.

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

Not stated on carton.

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 REACH AND SIGHT OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4028

UK authorised veterinary medicinal product

17. MANUFACTURER'S BATCH NUMBER

Batch No:

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Tetroxy L.A. 200 mg/ml Oxytetracycline Solution for Injection

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

Marketing authorisation holder and manufacturer responsible for batch release:

Bimeda Animal Health Limited,
2/3/4 Airton Close,
Tallaght,
Dublin 24,
Ireland.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tetroxy L.A. 200 mg/ml Oxytetracycline Solution for Injection

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

Active Substance

Oxytetracycline (as Oxytetracycline Dihydrate)	200 mg/ml .

Excipient(s)

Polyvinylpyrrolidone (K - 17)	Co-solvent	
N-Methyl Pyrrolidone	Co-solvent	370.0 mg/ml

4. INDICATION(S)

Tetroxy L.A. is indicated in the treatment and control of diseases caused by or associated with organisms sensitive to Oxytetracycline in cattle, sheep and pigs.

5. CONTRAINDICATIONS

Not recommended for cats, dogs, horses and donkeys.

6. ADVERSE REACTIONS

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

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, sheep and pigs.

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

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

It is recommended that the following amounts of Tetroxy L.A. at one site should not be exceeded:

Cattle and Sheep - 10 ml
Pigs - 5 ml
Pigs under 10 kg - maximum dose of 1 ml

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

9. ADVICE ON CORRECT ADMINISTRATION

Because of the sustained blood levels attained at the above dosage rates with Tetroxy L.A., this is a single dose treatment.

10. WITHDRAWAL PERIOD(S)

Cattle (meat & offal): 39 days
Pigs (meat & offal): 40 days
Sheep (meat & offal): 28 days
Do not use in animals producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25 °C.
Protect from light.
Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 28 days.
Discard unused material.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Prolonged use of anti-infectives may result in super infection by non-susceptible organisms. Photodermatitis may occasionally occur after treatment under strong exposure to sunlight.

Special precautions for use in animals:
Following withdrawal of the first dose, use the product within 28 days.
Not recommended in cases of renal impairment (see also 4.4 above). Discard unused material.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Take care to avoid accidental self injection. In case of contact with eyes or skin, wash immediately with plenty of water as irritation may occur. Wash hands after use.

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Women of childbearing age, pregnant women or women suspected of being pregnant should use the veterinary medicinal product with serious caution to avoid accidental self-injection.

Pregnancy and lactation:
The use of Tetroxy L.A. during the period of tooth development including late pregnancy may lead to discoloration.

The safety of the veterinary medicinal product has not been established in cattle, sheep and pigs during pregnancy, lactation or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Do not dilute. It is unwise to administer bacteriostatic and bactericidal antibiotics concurrently.

Overdose (symptoms, emergency procedures, antidotes):
Not applicable.

Incompatibilities:
Tetroxy L.A. should not be brought into contact with calcium solutions. Do not dilute.

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2023

15. OTHER INFORMATION

MA Number: Vm 50146/4028.

100ml amber Type II glass vials, fitted with bromobutyl rubber stoppers and sealed with plain aluminium caps containing a clear yellow to amber sterile aqueous solution.

To be supplied only on veterinary prescription. POM- V

Distributor:
Bimeda ®
Cross Vetpharm Group UK Ltd.,
Unit 2, Bryn Cefni,
Llangefni,
Anglesey, LL77 7XA,
United Kingdom.

Approved 25 January 2024