

PARTICULARS TO APPEAR ON THE OUTER PACKAGE - Carton 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetroxy LA 200 mg/ml solution for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Oxytetracycline 200 mg/ml

3. PACKAGE SIZE

Oxytetracycline 200 mg/ml

4. TARGET SPECIES

Cattle, sheep and pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle:

Meat and offal: 31 days

Milk: 10 days

Sheep:

Meat and offal: 9 days

Milk: 7 days

Pigs:

Meat and offal: 18 days

8. EXPIRY DATE

Exp. '(mm/yyyy)'

Shelf life after first opening the container: 28 days.
Once broached, use by

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C
Keep the vial in the outer carton in order to protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Ltd.

14. MARKETING AUTHORISATION NUMBER

Vm 50146/4021

15. BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – Label 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetroxy LA 200 mg/ml solution for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Oxytetracycline 200 mg/ml

3. TARGET SPECIES

Cattle, sheep and pigs.

4. ROUTES OF ADMINISTRATION

Intramuscular use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle:

Meat and offal: 31 days

Milk: 10 days

Sheep:

Meat and offal: 9 days

Milk: 7 days

Pigs:

Meat and offal: 18 days

6. EXPIRY DATE

Exp: '(mm/yyyy)'

Shelf life after first opening the container: 28 days.

Once broached, use by

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

Keep the vial in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Ltd.

9. BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Vetroxy LA 200 mg/ml solution for injection for cattle, sheep and pigs.

2. Composition

Each ml contains:

Active Substance:

Oxytetracycline 200.0 mg

Excipient:

Sodium formaldehyde sulfoxylate dihydrate 4.0 mg

Dimethylacetamide 470.0 mg

A clear amber solution.

3. Target species

Cattle, sheep and pigs.

4. Indications for use

The veterinary medicinal product is indicated for the treatment of infections caused by oxytetracycline susceptible bacteria in cattle, sheep and pigs as follows:

Cattle:

- Pasteurellosis and respiratory tract infections caused by *Mannheimia haemolytica* or *Pasteurella multocida*.
- Umbilical infections and septic arthritis caused by *Trueperella pyogenes*, *Escherichia coli* or *Staphylococcus aureus*.
- Clinical Mastitis caused by *Trueperella pyogenes*, *Escherichia coli*, *Staphylococcus aureus*, *Streptococcus agalactiae* or *Streptococcus uberis*.
- Metritis caused by *Escherichia coli*

Sheep:

- Pasteurellosis and respiratory tract infections caused by *Mannheimia haemolytica* or *Pasteurella multocida*.

- Umbilical infections and septic arthritis caused by *Trueperella pyogenes*- or *Escherichia coli*.
- Clinical Mastitis caused by *Trueperella pyogenes*, *Escherichia coli* or *Staphylococcus aureus*.
- Erysipelas caused by *Erysipelothrix rhusiopathiae*.
- The veterinary medicinal product can also be used for treatment and metaphylaxis of enzootic abortion in sheep caused by *Chlamydophila abortus*.

Pigs:

- Pasteurellosis and respiratory tract infections caused by *Mannheimia haemolytica* or *Pasteurella multocida*.
 - Umbilical infections and septic arthritis caused by *Trueperella pyogenes*, *Escherichia coli* or *Staphylococcus aureus*.
 - Clinical Mastitis caused by *Escherichia coli*.
 - Erysipelas caused by *Erysipelothrix rhusiopathiae*.
- Atrophic rhinitis caused by *Bordetella bronchiseptica* or *Pasteurella multocida*.

5. Contraindications

Do not use in horses, dogs and cats.

Do not use in animals with hepatic or renal damage.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:

None.

Special precautions for safe use in the target species:

Do not dilute the veterinary medicinal product.

If concurrent treatment is administered, use a separate injection site.

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

Official and local antimicrobial policies should be taken into account when the veterinary medicinal product is used.

Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to oxytetracycline and may decrease the effectiveness of treatment with other tetracyclines due to the potential for cross-resistance.

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

The excipient dimethylacetamide may damage unborn children; therefore, women of child bearing age must be very careful to avoid exposure via spillage onto the skin or accidental self-injection when administering the veterinary medicinal product. If you are pregnant, think you may be pregnant or are attempting to conceive, you should not administer the veterinary medicinal product.

This veterinary medicinal product may cause allergy-type reactions in sensitised people.

Those with known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product.

This veterinary medicinal product may cause skin and eye irritation. Avoid contact of the skin and eyes with the veterinary medicinal product. In case of accidental spillage onto skin or eyes, rinse the affected area with large amounts of water.

Take care to avoid accidental injection. In case of self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

Pregnancy and lactation

The safety of the veterinary medicinal product has not been tested in the target species.

The active substance, oxytetracycline, readily crosses the placenta and concentrations in the foetal blood may reach those of the maternal circulation, although the concentration is usually somewhat lower. Tetracyclines are deposited in teeth, causing discolouration, enamel hypoplasia and reduced mineralisation.

Tetracyclines can also retard foetal skeletal development. As such, the veterinary medicinal product should only be used in the last half of pregnancy when the benefits outweigh the foetal risks.

Oxytetracycline is excreted in milk; concentrations are generally low.

Interaction with other medicinal products and other forms of interaction:

Oxytetracycline should not be administered simultaneously with bactericidal antimicrobials, such as penicillins and cephalosporins.

Divalent or trivalent cations (Mg, Fe, Al, Ca) can chelate tetracyclines.

Overdose:

There is no known specific antidote, if signs of possible overdose occur treat the animal symptomatically.

Major incompatibilities:

The veterinary medicinal product should not be mixed with other veterinary medicinal products.

7. Adverse events

Cattle, Sheep and pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Hepatic toxicosis Blood dyscrasia
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction ¹
Undetermined frequency (cannot be estimated from the available data):	Photosensitivity Discoloured teeth ² Bone discolouration ² , delayed bone growth or healing ³

¹ A slight local reaction of a transient nature.

² In young animals, oxytetracycline can cause a yellow, brown or grey discolouration of bones and teeth.

³ May occur following a high dose or chronic administration.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably by a veterinarian, to either the marketing authorisation holder or its local representative, or the national competent authority via the national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

The recommended dose rate is 20 mg/kg bodyweight (i.e. 1 ml per 10 kg bodyweight) administered by deep intramuscular injection. The veterinary medicinal product is recommended for a single administration only.

The cap may be safely punctured up to 35 times. When treating groups of animals, use a draw-off needle.

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

Maximum volume to be administered per injection site:

Cattle : 20 ml

Pigs : 10 ml

Sheep: 5 ml

9. Advice on correct administration

See section 8.

10. Withdrawal periods

Cattle:

Meat and offal: 31 days

Milk: 10 days

Sheep:

Meat and offal: 9 days

Milk: 7 days

Pigs:

Meat and offal: 18 days

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.

Keep the vial in the outer carton in order to protect from light.

Shelf life after first opening the immediate packaging: 28 days.

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

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines that are no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 50146/4021

Package quantities: 100 ml amber type II glass vials sealed with a bromobutyl rubber stopper with aluminium overseals and packaged individually into outer cartons.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

Dopharma B.V.
Zalmweg 24, Raamsdonksveer,
4941 VX
Netherlands

Local representatives and contact details to report suspected adverse reactions:

Cross Vetpharm Group UK Limited (Trading as Bimeda)
Unit 2, Bryn Cefni Industrial Park
Llangefni, LL77 7XA
United Kingdom
Tel: 01248 725 400

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

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Gavin Hall
Approved: 18 February 2025