1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tetracure 200 mg/ml solution for injection for cattle, sheep and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Oxytetracycline (as dihydrate) 200.0 mg
(Equivalent to 216 mg oxytetracycline dihydrate)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium Formaldehyde Sulphoxylate Dihydrate	4.0 mg
Magnesium Oxide Light	
Dimethylacetamide	
Disodium Edetate	
Ethanolamine (for pH adjustment)	
Hydrochloric Acid, concentrated (for pH adjustment)	
Water for Injections	

A clear amber solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, sheep and pigs.

3.2 Indications for use for each target species

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*. The presence of the disease in the group must be established before the veterinary medicinal product is used.

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*.

3.3 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, to other tetracyclines or to any of the excipients.
Do not use in known cases of resistance to tetracyclines.

3.4 Special warnings

None.

3.5 Special precautions for use

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:
This veterinary medicinal product may cause sensitisation.
People with known hypersensitivity to tetracyclines, such as oxytetracycline, 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 accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

The excipient dimethylacetamide may damage the unborn child; 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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle, sheep and pigs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Photosensitivity[1], Hepatic disorder[1,2], Blood dyscrasia[1]
Undetermined frequency (cannot be estimated from the available data)	Application site reaction[3], Discoloured bones[4], Discoloured teeth[4], Delayed bone growth[5], Delayed healing[5]

[1]Tetracyclines have been associated with such reactions.
[2]Hepatotoxicity
[3]Slight, transient in nature
[4]Oxytetracycline given to young animals can cause a yellow, brown or grey discolouration of bones and teeth.
[5]High dose or chronic administration may delay bone growth or healing.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The veterinary medicinal product can be used during lactation.
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 delay foetal skeletal development. As such, the veterinary medicinal product should only be used in the last half of pregnancy following risk benefit assessment by the responsible veterinarian.

Oxytetracycline is excreted in milk; concentrations are generally low.

3.8 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.

3.9 Administration routes and dosage

Intramuscular use.
Deep intramuscular administration. The recommended dose rate is 20 mg of oxytetracycline/kg bodyweight (i.e. 1 mL of product per 10 kg bodyweight). 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.

Maximum volume to be administered per injection site:

Cattle : 20 ml
Pigs : 10 ml
Sheep : 5 ml

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Possible adverse reactions following overdose are listed in Section 3.6. There is no known specific antidote. If signs of possible overdose occur treat the animal symptomatically.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Cattle:
Meat and offal: 31 days
Milk: 10 days (240 hours)

Sheep:
Meat and offal: 9 days
Milk: 7 days (168 hours)

Pigs:
Meat and offal: 18 days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QJ01AA06

4.2 Pharmacodynamics

Oxytetracycline is a bacteriostatic antibiotic that inhibits protein synthesis in susceptible bacteria. Inside the cell it binds irreversibly to receptors on the 30S subunit of the bacterial ribosome where it interferes with the binding of the aminoacyl-transfer RNA to the acceptor site on the messenger RNA ribosome complex. This effectively prevents the addition of amino acids to the elongating peptide chain, inhibiting protein synthesis.

Oxytetracycline had been shown to be active in vitro against the following bacterial species: *Bordetella bronchiseptica, Trueperella pyogenes, Erysipelothrix rhusiopathiae, Escherichia coli, Mannheimia haemolytica, Pasteurella multocida, Staphylococcus aureus, Streptococcus agalactiae,* and *Streptococcus uberis*.

Multiple genes have been identified which mediate resistance to tetracyclines and these genes may be carried on plasmids or transposons between both pathogenic and non-pathogenic bacteria. The most

common mechanisms of resistance involve either the removal of the antibiotic from the organism by energy dependent efflux pumps or protection of the ribosome from binding by altered target sites. Resistance to one tetracycline confers cross-resistance across the whole group.

Oxytetracycline resistance has been identified in many veterinary pathogens; however, the prevalence of resistance varies widely between different locations. For veterinary isolates, the susceptible breakpoint is ≤ 2 μg/mL for bovine respiratory pathogens and ≤ 0.5 μg/mL for swine pathogens. For other isolates, the breakpoint for sensitive organisms in humans is used, which is ≤ 4 μg/mL for all organisms, except streptococci, which is ≤ 2 μg/mL (CLSI, 2007).

4.3 Pharmacokinetics

Maximum blood levels are achieved between 4 and 8 hours following intramuscular administration.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Amber type II glass vials of 100 ml sealed with a bromobutyl rubber stopper with aluminium overseals and packaged individually into outer cartons.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22033/068/001

8. DATE OF FIRST AUTHORISATION

05/02/2016

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

08/09/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).