Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
One ml contains:
Oxytetracycline (as dihydrate) 200.0 mg
(Equivalent to 216 mg oxytetracycline dihydrate)

Excipient:
Sodium Formaldehyde Sulphoxylate Dihydrate 4.0 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A clear amber solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, sheep and pigs.

4.2 Indications for use, specifying the 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 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 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*.

4.3 Contraindications

Do not use in horses, dogs and cats.
Do not use in animals with hepatic or renal damage.
Do not use in known 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special Precautions for Use in Animals

Do not dilute the product.
If concurrent treatment is administered, use a separate injection site.
Use of the 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 product is used.
Use of the 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 product may cause sensitisation.
People with known hypersensitivity to tetracyclines, such as oxytetracycline, should avoid contact with the product.
This product may cause skin and eye irritation.
Avoid contact of the skin and eyes with the 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.
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 product. If you are pregnant, think you may be pregnant or are attempting to conceive, you should not administer the product.

4.6 Adverse reactions (frequency and seriousness)

Occasionally a slight local reaction of a transient nature has been observed.
Tetracyclines have very rarely been associated with photosensitivity reactions, hepatotoxicity and blood dyscrasias.
Oxytetracycline given to young animals can cause a yellow, brown or grey discolouration of bones and teeth. High dose or chronic administration may delay bone growth or healing.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The 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 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.

4.8 Interaction with other medicinal products and other forms of interactions

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.

4.9 Amounts to be administered and administration route

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 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 : 20ml
Pigs : 10ml
Sheep : 5ml

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Possible adverse reactions following overdose are listed in Section 4.6. There is no known specific antidote, if signs of possible overdose occur treat the animal symptomatically.

4.11 Withdrawal period(s)

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Tetracyclines.
ATCvet Code: QJ01AA06

5.1 Pharmacodynamic properties

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).

5.2 Pharmacokinetic particulars

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Formaldehyde Sulphoxylate Dihydrate
Magnesium Oxide Light
Dimethylacetamide
Disodium Edetate
Ethanolamine (for pH adjustment)
Hydrochloric Acid, concentrated (for pH adjustment)
Water for Injections

6.2 Major incompatibilities

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

6.3 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.

6.4 Special precautions for storage

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

6.5 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.

6.6 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.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2, 3 & 4 Airton Close
Airton Road
Tallaght
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22033/068/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 05 February 2016
Date of last renewal: 05 February 2021

10 DATE OF REVISION OF THE TEXT

February 2021