

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Tetroxy Vet 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 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.

#### **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  $\leq 2 \mu\text{g/mL}$  for bovine respiratory pathogens and  $\leq 0.5 \mu\text{g/mL}$  for swine pathogens. For other isolates, the breakpoint

for sensitive organisms in humans is used, which is  $\leq 4 \mu\text{g/mL}$  for all organisms, except streptococci, which is  $\leq 2 \mu\text{g/mL}$  (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 25°C.  
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 Product 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

Tallaght  
Dublin 24  
Ireland

**8. MARKETING AUTHORISATION NUMBER**

Vm 50146/4008

**9. DATE OF FIRST AUTHORISATION**

18 February 2016

**10. DATE OF REVISION OF THE TEXT**

March 2021

Approved: 03/03/21

A handwritten signature in dark ink, appearing to read "D. Austin", with a horizontal line extending from the end of the signature.