



### **1.3 Product information**

#### **1.3.1 Summary of product characteristics**

##### **1 Name of the veterinary medicinal product**

Oxytetracycline 20% injection

##### **2 Qualitative and quantitative composition**

Active ingredients:

Oxytetracycline – 200 mg

##### **3 Pharmaceutical form**

Solution for injection.

##### **4. Clinical particulars**

###### **4.1 Target species**

Calves, cattle, goats, sheep and swine.

###### **4.2 Indications for use, specifying the target species**

Arthritis, gastrointestinal and respiratory infections caused by Oxytetracycline sensitive micro-organisms, like Bordetella, Campylobacter, Chlamydia, E.coli, Haemophilus, Mycoplasma, Pasteurella, Rickettsia, Salmonella, Staphylococcus and Streptococcus spp., in calves, cattle, goats, sheep and swine.

###### **4.3 Contraindications**

Hypersensitivity to tetracyclines.

Administration to animals with a seriously impaired renal and/or liver function.

Concurrent administration of penicillines, cephalosporines, quinolones and cycloserine.

###### **4.4 Special warnings for each target species**

None.

###### **4.5 Special precautions for use**

Special precautions for use in animals

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.



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

Take care to avoid accidental injection.

Wash hands after use. In case of contact with eyes or skin, wash immediately with plenty of water as irritation may occur.

#### **4.6 Adverse reactions (frequency and seriousness)**

After intramuscular administration local reactions can occur, which disappear in a few days.

Discoloration of teeth in young animals.

Hypersensitivity reactions.

#### **4.7 Use during pregnancy, lactation or lay**

Oxytetracycline can retard skeletal growth of the fetus if administered during pregnancy.

The use of tetracyclines during the period of tooth development, including late pregnancy, may lead to tooth discolouration.

Tetracyclines are excreted in milk.

The product should only be used according to the benefit/risk assessment by the responsible veterinary surgeon.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

Do not dilute or mix with other compounds.

#### **4.9 Amounts to be administered and administration route**

For intramuscular or subcutaneous administration:

General: 1 ml per 10 kg body weight.

This dosage can be repeated after 48 hours when necessary.

Do not administer more than 20 ml in cattle, more than 10 ml in swine and more than 5 ml in calves, goats and sheep per injection site.

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

There is no known specific antidote.

If signs of possible overdose occur, treat the animal symptomatically.

#### **4.11 Withdrawal period(s)**

Cattle milk: 8 days



Cattle meat: 35 days

Pig meat: 28 days.

## **5 Pharmacological properties**

Pharmacotherapeutic group: Antibacterial, anti-inflammatory

ATC vet code: QJ01AA56

### **5.1 Pharmacodynamic properties**

Oxytetracycline is active against a wide range of Gram positive and Gram negative pathogenic bacteria, and certain Rickettsia. 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 amino-acyl transfer RNA to the acceptor site on the messenger RNA ribosome complex. This effectively prevents the addition of the amino acids to the elongating peptide chain, inhibiting protein synthesis.

### **5.2 Pharmacokinetic particulars**

Oxytetracycline is widely distributed in the body with the exception of CSF and it binds to plasma proteins in a variable manner depending on the species (20-40%).

Oxytetracycline is excreted mainly unchanged via the renal route, some in faeces and milk. It is also excreted by the bile but a high proportion of oxytetracycline is reabsorbed by the small intestine (enterohepatic cycle).

## **6. Pharmaceutical particulars**

### **6.1 List of excipients**

N-Mehtylpyrrolidone

Magnesium oxide

Sodium formaldehyde sulfoxylate

Ethanolamine

Water for injection

### **6.2 Incompatibilities**

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

### **6.3 Shelf life**



2 years.

**6.4. Special precautions for storage**

Store in a cool dry place below 30°C, protected from light.

**6.5 Nature and composition of immediate packaging**

Glass bottles of 100ml, with rubber stoppers, sealed with aluminum caps.

**6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate**

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