

**PELANGI VET PHARMA SDN.BHD**  
Lot 8, PERDA Industrial Park, Lorong IKS, Simpang Ampat B,  
14100 Simpang Ampat, S.P.S, Pulau Pinang, Malaysia

## **PRODUCT LITERATURE**

### **1.Product Name:**

**PVP- OXYTETRACYCLINE 20% W/W POWDER**

### **2. Each 1 g powder contains:**

#### **Active Ingredient:**

Oxytetracycline Hydrochloride BP                      218.90 mg  
(Equivalent to Oxytetracycline 200 mg)

### **3. Product Description:**

Slightly Yellow Coloured Powder

### **4. Target Species:**

Cattle (over 160 kg bodyweight), Calves, Pigs

### **5. Pharmacodynamics:**

Oxytetracycline is a member of the tetracycline group of antibiotics and is produced by fermentation of *Streptomyces rimosus*. It possesses broad spectrum antimicrobial activity against a wide range of gram +ve and gram -ve bacteria, certain *Mycoplasma* spp, protozoa and rickettsiae. Oxytetracycline is bacteriostatic in action and acts by inhibiting protein synthesis in the bacterial cell.

### **6. Pharmacokinetics:**

When given by mouth in solution oxytetracycline acts locally in the gut and is absorbed into the bloodstream and distributed to the tissues especially lung tissue. Blood and tissue levels are measurable with the sensitive HPLC assay.

## **7. Indication:**

Cattle (over 160 kg bodyweight): Respiratory disease.

Calves: Bacterial enteritis.

Pigs: Respiratory disease.

## **8. Recommended Dose:**

For oral administration in the drinking water or as a drench.

Treatment period 3-5 days.

**Calf:** 9-18 mg/kg/day oxytetracycline hydrochloride twice daily.

**Ruminating cattle:** 2-4 mg/kg/day oxytetracycline hydrochloride twice daily.

**Pigs:** 10-30 mg/kg/day oxytetracycline hydrochloride

4-12.5 g oxytetracycline hydrochloride per 10 gallons. 1 x 500 g pack medicates 248 gallons of drinking water at the lower dosage level.

## **9. Mode of Administration:**

Orally via drinking water or as a drench.

## **10. Contraindications:**

None.

## **11. Warning & Precautions:**

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

Acutely ill animals are unlikely to consume an adequate dose unless treated by drinking water or drench methods. When given via the drinking water remove all other sources of water until the medicated water has been consumed.

Following oral dosage in ruminants, changes in the ruminal flora may occur but these have generally been found to be of a transitory and reversible nature. Administration at the recommended dosage will usually result in only a small depression of cellulose digestion.

Bacterial resistance may develop after long term use of oxytetracycline. This is particularly likely in enterobacteria and *Salmonella*, many of which are already resistant. *Salmonella* shedding in treated animals will continue where organisms are resistant.

#### **Special precautions for use in animals**

None.

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

If you know you are hypersensitive (allergic) to oxytetracycline, do not handle the product. When handling the product avoid inhalation of dust by wearing a disposable half-mask respirator conforming to European Standards EN 149 (FFP2) or a non-disposable respirator to European Standards EN 140 with a filter to EN 143. Wear gloves and avoid contact with skin and eyes. In case of contact, wash area immediately with fresh water. If irritation persists seek medical attention. Hands and exposed skin should be washed thoroughly after use.

#### **12. Drug Interactions:**

Interactions may occur with solutions with high calcium, magnesium or sodium content.

#### **13. Pregnancy & Lactation:**

No adverse effects.

#### **14. Side effects:**

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

#### **15. Symptoms & Treatment of Overdose:**

The safety margin of oxytetracycline in the target species is very wide and toxic signs are unlikely to be seen. Large overdoses are potentially nephrotoxic

#### **16. Withdrawal Period:**

Cattle: Meat: 10 days

Milk: zero hours. Milk may not be taken for human consumption during treatment.

Pigs: 7 days

**17. Storage Conditions:**

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

**18. Dosage Form:**

Powder in the form of powder to be dissolved in the water.

**19. Packaging:**

- i) Pack of 1 kg in HDPE Plastic Container
- ii) Pack of 500 g in HDPE Plastic Container
- iii) Pack of 1 kg pack in Aluminium Sheet Lacquered
- iv) Pack of 500 g pack in Aluminium Sheet Lacquered

**20. Disposal of Container:**

To be disposed as per local authority requirement.

**21. Expiry Date:**

2 years from date of manufacturing.

**22. Shelf life after reconstitution or dilution:**

To be used within 24 hours after dilution.

**Manufactured & Distributed by :**

**Pelangi Vet Pharma Sdn Bhd.** (665097K)  
Lot 8, PERDA Industrial Park,  
Lorong IKS, Simpang Ampat B  
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