

**PELANGI VET PHARMA SDN.BHD** <sup>(665097-K)</sup>  
LOT 8, PERDA Industrial Park, Lorong IKS, SimpangAmpat B,  
14100 SimpangAmpat, S.P.S, Pulau Pinang, Malaysia

## **PRODUCT LITERATURE**

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

**PVP- NEOMYCIN 60% W/W POWDER**

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

#### **Active Ingredient:**

Neomycin Sulphate BP 857.0mg  
(Equivalent to Neomycin 600.0mg)  
(Equivalent to Neomycin 557,050 IU)

### **3. Description**

A white to light yellowish powder

### **4. Target Species**

Cattle (calves), pigs (weaned and fattening pigs), chickens, layer hen, ducks, turkeys, turkey hen, goose, quail and partridge.

### **5. Pharmacodynamics:**

Neomycin is an antibiotic from the aminoglycoside family. Aminoglycosides have a broad antibacterial spectrum with good activity against Gram negative species, especially *Escherichia coli* and less activity against Gram positive species. This class of antimicrobials has no effect against anaerobic bacteria.

Neomycin binds to the 30S subunit of the bacterial ribosome which disturbs the reading of the constituent code of the RNA messenger, and finally synthesis bacterial protein. At high concentrations, it has been shown that aminoglycosides damage the cell wall, conferring bactericidal and bacteriostatic properties.

The resistance mechanisms are complex and differ between aminoglycoside molecules. Four mechanisms of resistance have been identified: changes of the ribosome, reduction of permeability, inactivation by enzymes and substitution of the molecular target. The common mechanism of resistance is the production of aminoglycosides modifying enzymes. These resistance mechanisms can be located in mobile genetics element increasing the likelihood of spread of aminoglycoside resistance as well as co and cross-resistance.

#### 6. Pharmacokinetics:

Neomycin is poorly absorbed from the gastrointestinal tract. Absorption from the gastrointestinal tract can be significant in neonates. 90% of neomycin is excreted in the feces after oral administration.

#### 7. Indication:

Calves, pigs (weaned and fattening pigs), chickens, layer hen, ducks, turkeys, turkey hen, goose, quail and partridge: For treatment of gastrointestinal infections caused by *E.Coli* sensitive to neomycin.

#### 8. Recommended Dose:

In drinking water/milk use:

25000 IU of neomycin per kg bodyweight per day for 3 to 4 consecutive days, corresponding to 4.5g of PVP-Neomycin 60% w/w powder per 100kg bodyweight per day for 3 to 4 days.

The following formula may be used to calculate the required amount of PVP-Neomycin 60% w/w Powder in g per litre drinking water/milk:

$$\frac{\text{g of product per l drinking water/milk}}{\text{Mean daily water/milk consumption (l) per animal}} = \frac{\text{g of product/kg b.w./day} \times \text{mean b.w. (kg) of animals to be treated}}{\text{Mean daily water/milk consumption (l) per animal}}$$

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of neomycin has to be adjusted accordingly.

For the administration of the product commercially available dosing pumps can be used.

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

Oral

## **10. Contraindications:**

Do not use in case of hypersensitivity to the active substance, to aminoglycosides or to the excipient.

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

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

Medicated drinking water intake can be affected by the severity of the disease. In case of insufficient intake of water, animals should be treated parenterally.

### **Special precautions for use**

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

Powder for oral solution that is to be dissolved in water and cannot be used as it is. Special care should be taken when considering to administer the product to the newborn calf due to the known higher gastrointestinal absorption of neomycin in neonates. This higher absorption could lead to an increased risk of oto- and nephrotoxicity. The use of the product in neonates should be based on the benefit/risk determination from the attending veterinarian.

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, national and regional antimicrobial policies should be taken into account when the product is used.

Use of the product deviating from the instructions given in the Package Insert may increase the prevalence of bacteria resistant to neomycin and may decrease the effectiveness of treatment with aminoglycosides due to the potential for cross resistance.

#### **ii) Special precautions to be taken by the person administering the product to animals**

Wash hands after use.

People with known hypersensitivity to aminoglycosides should avoid contact with the veterinary medicinal product.

If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

**iii) Other Precautions**

None.

**12. Drug Interactions:**

General anaesthetics and muscle relaxing products increases the neuro-blocking effect of aminoglycosides. This may cause paralysis and apnoea. Special care should be taken when using concurrently with strong diuretics and potentially oto- or nephrotoxic substances.

**13. Pregnancy & Lactation:**

Laboratory studies in animals have not produced any evidence of teratogenic effects of neomycin. The safety of the veterinary medicinal product has not been evaluated in the target species. The use will be accordingly to the benefit/risk assessment by the responsible veterinarian.

**14. Side effects:**

None known.

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

Nephrotoxic and/or ototoxic effects may occur in case of an accidental overdose.

**16. Withdrawal Period:**

**Cattle:** (Meat & offal)- 14 days

**Pigs:** (Weaned & fattening pigs)- 3 days

**Chickens, layer hen, ducks, turkeys, turkey hen, goose, quail and partridge:** (Meat & offal) - 14 days  
Eggs: zero 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 water.

**19. Packaging:**

- (i) Pack of 1kg in HDPE Plastic Container along with caps.
- (ii) Pack of 500g in HDPE Plastic Container along with caps.
- (iii) Pack of 1kg in Aluminium Sheet Lacquered .
- (iv) Pack of 500g 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.** (665097-K)  
Lot 8, PERDA Industrial Park,  
Lorong IKS, SimpangAmpat B  
14100 SimpangAmpat,  
S.P.S Pulau Pinang, Malaysia

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