



Veterinary Use Only

Metapleu Plus Florfenicol 20% w/w Premix

1. Brand or Product Name / Name and Strength of Active Substance(s)

Metapleu Plus Florfenicol 20% w/w Premix

Each 1kg contains:

Florfenicol 200g

2. Product Description : Pale yellow to brown powder

3. Pharmacodynamics/Pharmacokinetics/Environmental Properties

Pharmacodynamics :

Florfenicol is a broad-spectrum synthetic antibiotic active against most Gram-positive and Gram-negative bacteria isolated from domestic animals. Florfenicol acts by inhibition of protein synthesis at the ribosomal level and is bacteriostatic. However, bactericidal activity has been demonstrated in-vitro against *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*.

Pharmacokinetics :

The pharmacokinetic was evaluated in swine following oral gavage dosing (15 mg/kg), intravenous (IV) dosing (15 mg/kg), and during a 5-day course of ad libitum administration in drinking water (100 ppm). Despite the rapid elimination seen after IV injection or oral gavage dosing, when administered in medicated drinking water, florfenicol concentrations in the serum of most swine were maintained well above 1.0 mcg/mL for the majority of the 5-day dosing interval. These results are consistent with product effectiveness when administered in drinking water concentrations of 100 ppm over a 5-day dosing period.

Although the extent of oral drug absorption (F) tended to be variable (24% to 97% following a single oral gavage dose), florfenicol was rapidly absorbed. Its terminal elimination half-life (T_{1/2}) was also rapid, ranging between 2 to 3 hours. Since the florfenicol steady state volume of distribution (VDSS) closely approximates that of total body water, peripheral tissue concentrations are expected to be similar to those concentrations observed in serum.

4. Indication

For use in the treatment of pig respiratory disease associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Mycoplasma spp.* and *Streptococcus suis* Type 2.

5. Recommended Dosage / Mode of Administration

Mix with animal feed.

10 mg florfenicol/ kg body weight per day for 5 days.

6. Contraindications

Do not use in case of hypersensitivity to florfenicol or any of the excipients.

Do not feed to birds intended for breeding purposes.

7. Warnings and Precautions

- Excessive overdose may exhibit transient diarrhea.
- Use by or on the order of a licensed veterinarian.
- Read full directions before use.
- In case of accidental eye exposure, flush immediately with water for 15 minutes and consult a physician if irritation persists.
- In case of accidental skin exposure, wash with soap and water.
- Please refer the withdrawal period before animal is slaughtered for human consumption.
- Keep out of reach of children/ Jauhi ubat daripada kanak-kanak.

8. Interactions with Other Medicaments

No specific drug interactions for florfenicol were located, but the drug may behave similarly to chloramphenicol. If so, florfenicol could antagonize the bactericidal activity of the penicillins or aminoglycosides. This antagonism has not been demonstrated in vivo, and these drug combinations have been used successfully many times clinically.

9. Statement on usage during pregnancy and lactation

Studies in laboratory animals have not revealed any evidence of embryo- or foeto-toxic potential. However, the safety of the product in sows during pregnancy and lactation has not been demonstrated. Use of the product during pregnancy and lactation is therefore not recommended.

10. Adverse Effects/Undesirable Effects

Commonly observed adverse effects are transient diarrhoea and/or peri-anal and rectal erythema/oedema which may affect 50% of the animals. These effects can be observed for one week. Transient swelling lasting up to 5 days may be observed at the site of injection. Inflammatory lesions at the injection site may be seen up to 28 days.

11. Overdose and Treatment

In swine after administration of 3 times the recommended dose or more a reduction in feeding, hydration and weight gain has been observed.

After administration of 5 times the recommended dose or more vomiting has also been noted.

12. Withdrawal Period

Meat : Remove all medicated feed 12 days before slaughter for human consumption.

13. Storage condition

- Store in a room temperature, protected from light.
- Do not store above 30°C.

14. Dosage Forms and packaging available

500gm, 1kg, 5kg, 10kg, 20kg

15. Name and Address of manufacturer/marketing authorization holder

Nutri Pharmax Sdn Bhd

6, Lorong Serunai 1, Valdor Sungai Bakap, 14200 Sungai Jawi, Pulau Pinang, Malaysia.

16. Date of Revision of Package Insert : 09 April 2020



Manufactured by

KBNP, INC.

235-9 Chusaro, Sinam, Yesan,
Chungnam, Korea



Distributed by

Nutri Pharmax Sdn.Bhd.

6, Lorong Serunai 1, Valdor Sungai Bakap,
14200 Sungai Jawi, Pulau Pinang, Malaysia
Tel: +604-582 9377