

Veterinary Use Only

Metapleu Florfenicol 10% w/v Oral Solution

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

Metapleu Florfenicol 10%w/v Oral Solution

Each liter contains : Florfenicol 100g

2. Product Description : Pale yellow to brown liquid

3. Pharmacodynamics/Pharmacokinetics/Environmental Properties

Pharmacodynamics :

Florfenicol is a broad-spectrum synthetic antibiotic in the phenicol group that is 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* when florfenicol is present at concentrations above the MIC for up to 12 hours. In-vitro testing has shown that florfenicol is active against the bacterial pathogens most commonly isolated in respiratory diseases in pigs, including *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*.

Pharmacokinetics :

After administration to pigs by gavage at 15 mg/kg under experimental conditions, absorption of florfenicol was variable but peak serum concentrations of approximately 5 µg/mL were reached approximately 2 hours after dosing. The terminal half-life was between 2 and 3 hours. When pigs were given free access, for 5 days, to water medicated with Metapleu Oral Solution at a concentration of 100 mg florfenicol per litre of water, serum concentrations of florfenicol exceeded 1 µg/mL for the entire 5 day treatment period except for a couple of short excursions below 1 µg/mL. After absorption and distribution, florfenicol is extensively metabolised by pigs and rapidly eliminated, primarily in urine. After parenteral dosing of florfenicol to pigs, it has been shown that lung concentrations are similar to serum concentrations.

4. Indication

Swine: For the treatment of pig respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*.

Poultry: Broiler chicken- For the treatment and control of air sacculitis associated with *E.coli* susceptible to florfenicol.

5. Recommended Dosage / Mode of Administration

Administer via drinking water

For swine: 10mg florfenicol/kg bodyweight/day for 5 days. To treat pigs eating 5% of their bodyweight at the recommended dose of 10mg/kg, incorporate the product into the complete ration at a concentration of 200ppm. Feed as the sole ration for a period of 5 consecutive days.

For broiler chicken: 100ppm (100mg/mL) for 3 consecutive days in drinking water. This dosage rate is equivalent to 35mg/kg bodyweight of birds.

6. Contraindications

Do not administer animals with established hypersensitivity to florfenicol.

Do not administer in cases of previous allergic reactions to florfenicol.

Do not use to birds intended for breeding purpose.

7. Warnings and Precautions

- Should be used in conjunction with susceptibility testing.
- Inappropriate use may increase the prevalence of bacteria resistant to florfenicol.
- In case of consecutive administration, transitory inflammation at the anus site may occur.
- Do not use in layers producing eggs for human consumption.
- Treatment should not exceed 5 days.
- Use by veterinarian's instruction, and veterinary use only.
- Use only in animal mentioned on label.
- Do not get in eyes, on skin or clothing.
- If in eyes and skin, rinse immediately with plenty for more than 15 minutes of water and call a physician immediately.
- 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. Other antibiotics that bind to the 50S ribosomal subunit of susceptible bacteria (erythromycin, clindamycin, lincomycin, tylosin, etc.) may potentially antagonize the activity of chloramphenicol or vice versa, but the clinical significance of this potential interaction has not been determined.

9. Statement on usage during pregnancy and lactation

Studies in laboratory animals have not revealed any evidence of potential embryotoxic or foetotoxic effect of florfenicol. The safety of the veterinary medicinal product in sows has not been established during pregnancy and lactation. The use is not recommended during pregnancy and lactation.

10. Adverse Effects/Undesirable Effects

- Reduction of water consumption, transient
- Decreased food consumption, transient
- Dark brown faeces
- Diarrhea
- Perianal inflammation which may affect approximately 40% of the animals, transient.
- In a few of the affected animals, prolapse of the rectum that resolves without treatment may be observed.

11. Overdose (symptoms, emergency procedures, antidotes), if necessary

In case of consecutive administration, transitory inflammation at the anus site may occur.

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(s)

Swine – 12 days, Broiler chicken– 5days

13. Dosage Forms and packaging available

500ml, 1L, 5L

14. 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.

15. Date of Revision of Package Insert : 04 March 2019

Amend to new address

Manufactured by
 **KBNP, INC.**
 235-9 Chusaro, Sinam, Yesan,
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190307

Distributed by
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