SN-FLORFENICOL 5%w/w

ORAL POWDER

(FOR VETERINARY USE ONLY)

COMPOSITION

Florfenicol ..... 50 mg/g

PRODUCT DESCRIPTION

The finished product is a white color powder.

TARGET SPECIES

Pigs (Fattening pigs)

PHARMACODYNAMIC

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.

PHARMACOKINETIC

After administration to pigs by gavage at 10 mg/kg under experimental conditions, absorption of florfenicol was variable but peak serum concentrations of approximately 5µg/ml were reached approximately 3 hours after dosing. The terminal half-life was between 3 and 4 hours.

When pigs were given free access, for 5 days, to feed medicated with florfenicol (premix for medicated feeding stuff) at the recommended dose of 10 mg/kg serum florfenicol concentrations exceeded 1 µg/ml for more than 16 hours each day of treatment.

Florfenicol is well absorbed when administered orally and following distribution it is rapidly eliminated in the urine and faeces in a ration of 3:1. A fraction is excreted unchanged and the rest is metabolised into 5 major metabolites.

INDICATIONS

In fattening pigs:

For the treatment and prevention of swine respiratory disease in infected herds due to *Pasteurella multocida* susceptible to florfenicol. The presence of the disease should be established in the herd before initiating preventive treatment.

WARNINGS AND PRECAUTIONS

1. Special warnings for each target species:

Animals showing a decreased appetite and/or a poor general condition should be treated by the parenteral route.

2. Special precautions for use:

i. Special precautions for use in animals:

The product should be used in conjunction with susceptibility testing and take into account official and local policy relating to the use of antimicrobials.

Use of the product deviating from the instructions may increase the prevalence of bacteria resistant to the florfenicol and may decrease the effectiveness of treatment with other amphenicols, due to the potential for crossresistance.

Treatment should not exceed 5 days.

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

Skin sensitisation may occur.

Avoid skin contact.

Handle this product with care to avoid exposure during incorporation of premix into feed and administration of medicated feeding stuff to animals, taking all recommended precautions.

Wear either a disposable half-mask respirator or a non-disposable respirator with a filter, chemically resistant gloves, protective coveralls and goggles while incorporating the premix into feed.

Wear gloves and do not smoke, eat, or drink when handling the product or medicated feeding stuff.

Wash hands thoroughly with soap and water after use of the product or medicated feeding stuff.

Rinse thoroughly with water in case of exposure.

If you develop symptoms following exposure such as skin rash, you should seek medical advice immediately and show and take the package leaflet or the label to the physician.

- Keep medicine out of reach of children.
- Jauhkan ubat dari kanak-kanak

CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance, or to any of excipients.

Do not use in case of known resistance to florfenicol.

ADMINISTRATION & DOSAGE

To be administered orally, in medicated feeding stuff.

Dosage: 10 mg of florfenicol per kg body weight (bw) (equivalent to 200 mg the product) per day administered for 5 consecutive days.

Administration: For a daily feed intake of 50 g/kg bodyweight, this dosage corresponds to a rate of incorporation of 4 kg of product per tonne of feed, i.e. 200 ppm of florfenicol.

The rate of incorporation of the product in the feed may be increased in order to achieve the required dosage on a mg/kg bodyweight basis and to take into account the actual feed intake. Thus, the inclusion level may need adjusting as follows to give the correct dose.

$$\frac{\text{200 mg of the product per kg body weight and day} \times \text{Average pig body weight (kg)}}{\text{Average daily feed intake (kg/animal)}} = \text{mg the product per kg of feed}$$

The maximum rate of incorporation is 10 kg/tonne (500 ppm of florfenicol), higher rates of inclusion may lead to poor palatability and decreased food consumption.

INTERACTION WITH OTHER MEDICAMENTS

No data available

PREGNANCY AND LACTATION

The safety of the veterinary medicinal product has not been established in sows during pregnancy and lactation.

Do not use in pregnant and lactating sows.

Do not use in breeding boars.

OVERDOSE AND TREATMENT

In the event of overdose, a reduction in food and water consumption, together with a decrease in bodyweight may be observed. There may be an increase in refused feed and an increase in serum calcium.

SIDE EFFECT

Commonly observed adverse effects are diarrhoea perianal inflammation and rectal eversion. These effects are transient, resolving on cessation of treatment. Increased serum calcium may also be observed.

WITHDRAWAL TIME

Meat and offal: 14 days

SHELF LIFE: 36 months

SHELF LIFE after first opening & reconstitution: 24 hours

STORAGE

Store at temperature not exceeding 30°C. Strictly avoid light & heat exposure.

PACKAGING

The powder filled 1 kg in aluminum foil.

DATE OF REVISION: 01 Feb 2019

Product registration holder & Manufactured by:

SHENNONG ANIMAL HEALTH (M) SDN BHD
神農動物保健(馬)有限公司
No. 2, 4, 6, 8 & 10, Jalan Industri USJ 1/19,
Taman Perindustrian USJ 1,
47610 Subang Jaya, Selangor.