Veterinary Package Insert

Product Name:
DEXFLORCOL 200MG/ML SOLUTION

Product Description:
Light yellow colour solution, which contains 200mg of Florfenicol and 5mg of Benzyl Alcohol in 1ml.

Target Species:
Swine, others: pigs

Pharmacodynamics:
Florfenicol is a synthetic broad-spectrum antibiotic that has activity against a wide range of Gram-positive and Gram-negative bacterial species. It acts by inhibiting bacterial protein synthesis, and is generally considered to have a bacteriostatic action.
Florfenicol is a derivative of thiamphenicol, in which the hydroxyl group has been replaced with fluorine. This makes it effective against chloramphenicol resistant, acetyl transferase producing bacteria.
Laboratory tests have confirmed the activity of florfenicol against *Actinobacillus pleuropnemoniae and Pasteurella multocida* in swine.
Resistance to florfenicol mainly comes from the presence of specific (e.g. florR) or multi-substance (e.g. AcrAB-TolC) efflux pumps. The genes corresponding to these mechanisms are coded on genetic elements such as plasmids, transposons or gene cassettes. Cross resistance with chloramphenicol is possible.

Pharmacokinetics:
Florfenicol is well distributed to most body tissues. The maximum concentration is reached in kidney, liver, bladder, lung and in intestines. Approximately 50% of florfenicol is excreted from the organism unchanged. The remaining part is excreted as a metabolite (mainly florfenicol amine).

Indications:
Treatment and metaphylaxis of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* susceptible to florfenicol. The presence of the disease in the herd should be established before initiating metaphylaxis.

Recommended Dosage:
For in drinking water use.
The recommended dose is 10 mg florfenicol per kg body weight daily (corresponding to 5 ml of the product / 100 kg b.w.) given for 5 consecutive days.
The uptake of medicated water depends on several factors including the clinical state of the animals and local conditions such as ambient temperature and humidity. In order to obtain the correct dosage water uptake has to be monitored and the concentration of florfenicol has to be adjusted accordingly. If however it is not possible to obtain sufficient uptake of medicated water animals should be treated parenterally.
Based on the recommended dose, and the number and weight of the animals to be treated, the exact daily amount of the veterinary product should be calculated according to the following formula:

$$\frac{\text{5 ml product per 100 kg b.w. per day} \times \text{mean body weight (kg) of animals to be treated}}{\text{Mean daily water intake (litre) per animal}} = \text{X ml product per litre drinking water}$$

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
The appropriate quantity of medicated water should be prepared based on the daily water intake.
The veterinary medicinal product should be added to the drinking water by thorough stirring until the product is completely dissolved. Sufficient access to the water supply should be available for the animals to be treated to ensure adequate water intake. No other source of drinking water should be available during the medication period. In free range husbandry systems animals should be housed during treatment.
The water supply should be cleaned appropriately after the end of the medication period to avoid intake of sub-therapeutic amounts of active substance.
FOR PROPORTIONER:
1. Introduce the amount of Dexflorcol 200 mg/ml oral solution in the proportioner and dilute with drinking water as follows (examples):

Weight of animals	Amount of product	Amount of water (corr. to 1 mg florfenicol/ml of water)
500 kg	25 ml	5 L
1000 kg	50 ml	10 L
10,000 kg	500 ml	100 L

2.Mix thoroughly
3.Set the proportioner on 10 %.
4.Turn on the proportioner.
Warning: Solutions with concentrations higher than 1.2 g of florfenicol per litre precipitate.

Mode of Administration:
Oral

Contraindications:
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in boars intended for breeding purposes. Studies in rats have revealed evidence of potential adverse effects on the male reproductive system.

Warning and Precautions:
Special Warning for each Target Species
The treated animals should be placed under special observation. On each of the three or five days of treatment, unmedicated drinking water should not be given until the full daily amount of medicated drinking water has been ingested by the animals.
If there are no signs of improvement after three days of treatment, the diagnosis should be reviewed and, if necessary, the treatment changed.
In case of insufficient water intake, animals should be treated parenterally.
Special precautions for use in animals
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal.
Use of the product deviating from the instructions given may increase the prevalence of bacteria resistant to the florfenicol.
Official and local antimicrobial policies should be taken into account when the product is used.
Special precautions to be taken by the person administering the veterinary medicinal product to animals
This product may cause hypersensitivity (allergy).
People with known hypersensitivity to florfenicol, benzyl alcohol or propylene glycol should avoid contact with the product.
Pregnant women and women of child-bearing age should avoid working with this product.
Contact of the product or the medicated drinking water with skin and eyes should be avoided.
Personal protective equipment consisting of protective gloves, coverall and safety glasses should be worn when handling and mixing the product.
Do not smoke, eat or drink when handling the product or mixing the medicated drinking water.
In case of accidental spillage into eyes, wash them immediately with water.
In case of contact with skin, wash the affected area immediately and remove any contaminated clothing.
If you develop symptoms following exposure such as skin rash, seek medical advice and take the package leaflet or the label with you.
Wash hands after use.

Interactions with Other Medicaments
No data available

Pregnancy and Lactation:
As no studies have been performed in pigs during pregnancy and lactation, do not use the product in pregnant or lactating animals.

Adverse Effects:
A slight reduction of water intake by the animals, dark brown faeces and constipation may be observed during treatment.
Peri-anal erythema and soft faeces may occasionally occur after using the veterinary medicinal product. These effects are transient, short-term and do not affect the general condition of the animals.
Prolapse of the rectum that resolves without treatment may be observed.

Symptoms and Treatment of Overdose:
In case of overdosing, a decrease in weight gain, water intake, peri-anal erythema and oedema and modification of some haematological and biochemical parameters indicative of dehydration may be observed.

Withdrawal Period:
Pigs- Meat and offal: 23 days

Packaging:
Packed in 1L plastic HDPE bottle with screw cap

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

Shelf Life
Two years from date of manufacturing
To be used within 24 hours after first opening of container.
To be used within 24 hours after dilution.

Product Registration Holder
DEXCHEM INDUSTRIES SDN. BHD.
(Company No.: 555717-U)
No. 5, 11 & 11A, Lorong Cherok To'kun Jaya 2, Kawasan Perindustrian Cherok To'kun, 14000 Bukit Mertajam, Pulau Pinang, Malaysia.

Manufactured and Distributed by:
DEXCHEM INDUSTRIES SDN. BHD.
(Company No.: 555717-U)
No. 6 & 8, Jalan Industri Cherok To'kun2, Taman Industri Cherok To'kun,14000 Bukit Mertajam, Pulau Pinang, Malaysia.

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