

For Veterinary Use Only.

FENEROL[®]

30 % Oral Solution

Veterinary Systemic Antibacterial

COMPOSITION

Fenerol 30% Oral Solution is a light yellow colored clear solution containing 300 mg florfenicol in each ml.

PHARMACOLOGIC PROPERTIES

Florfenicol takes place in fenicol group. It is a tiamfenicol derivative and is distinguished from tiamfenicol by having fluorine in 3'-carbon atom instead of hydroxile group. It is a synthetic bacteriostatic antibiotic having a wide spectrum. It inhibits protein synthesis by binding 50 S ribosomal sub-units of 70 S ribosome of bacteria.

Primarily sensitive bacteria are:

Gram-positive bacteria: Actinomyces sp., Corynebacterium sp., Erysipelothrix rhusiopathie, Listeria monocytogenes, most Staphylococcus sp. and Streptococcus sp. Gram-negative bacteria: Actinobacillus sp., Bordetella bronchiseptica, Enterobacteraceae (E.coli, Klebsiella sp., Proteus sp., Salmonella sp.), Haemophilus sp., Leptospira sp., Moraxella sp., Pasteurella sp.. All anaerobic bacteria are generally sensitive. Florfenicol has strong antibacterial efficacy on E. coli causing colibacillosis especially in poultry. When administered orally, it is rapidly absorbed through digestive track and distributed to whole body particularly to lungs, liver, and kidneys. After an administration with a dose of 20 mg/kg live weight, 97% of the drug is excreted in urine, while the remaining part is excreted in faeces. In urine, 52% of it is excreted as unchanged, as oxamic acid (25%) and as Florfenicol base (7.5%). Protein binding ratio varies between 12,7% and 18,3%.

AREA OF USE / INDICATIONS

Fenerol 30% Oral Solution is used in broiler chickens for treatment of respiratory track diseases (air sacculitis) caused by E. coli and of coli septicemia.

USAGE AND DOSAGE

Unless recommended otherwise by veterinary surgeon, Fenerol 30% Oral Solution is administered in broiler chickens at a dose of 30 mg/kg florfenicol live weight/day for 3 days. Accordingly, 150 ml or 300 ml of Fenerol 30% oral solution is added in drinking water for 1500 kg and 3000 kg live weight, respectively. Drinking water should be prepared fresh everyday during the treatment.

UNDESIRE/SIDE EFFECTS

No side effects were reported in chicken if used in treatment dose and for the recommended treatment period.

DRUG INTERACTIONS

Fenerol 30% should not be used in combination with other diluted drugs.

WARNINGS FOR DRUG RESIDUES IN FOOD

Withdrawal period: Chickens should not be sent for slaughtering during treatment and before 5 days after the last drug administration. The drug should not be used in layer chickens whose eggs are offered for human consumption.

CONTRAINDICATIONS

It has no contraindications at the recommended dose and period.

GENERAL WARNINGS

Consult your veterinary surgeon before using and in case an unexpected effect is observed. Keep out of reach of children.

PRECAUTIONS TO BE TAKEN BY THE USER

Rinse with plenty of water in case of contact with eyes or skin. Do not eat or drink during administration.

STORAGE CONDITIONS AND SHELF LIFE

Shelf life is 2 years as of the production date. Protect from light. Solution is clear and has a color between pale yellow and yellow. Change in color does not have any effects on the strength of the drug. Store at room temperature (15-25°C).

COMMERCIAL PRESENTATION FORM

Offered for market in high-density polyethylene white plastic packages of 250, 1000 and 2500 ml without boxes.

PLACE AND CONDITIONS OF SALE

Sold with Veterinary Surgeon's prescription in pharmacies and veterinary surgeries (VPS).

APPROVAL DATE OF PACKAGE INSERT: 20.04.2009

MINISTRY OF AGRICULTURE AND RURAL AFFAIRS MARKETING AUTHORIZATION DATE AND NO:

13.04.2009-21/019

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

Alke Sağlık Ürünleri San. ve Tic. A.Ş

Dolayoba, Çınardere Mh. 3. Petek Sk. No: 18, 34896 Pendik-ISTANBUL

NAME AND ADDRESS OF MANUFACTURER COMPANY:

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Merkez Organize Sanayi Bölgesi 2. Kısım 10. Cadde No:7 Tokat