

# FLORCOL 30%

## Oral Solution

### (Containing Florfenicol 30% Activity)

#### COMPOSITION: Contains per litre

Florfenicol.....	300g activity
Pyrrolidone.....	250ml
Propylene Glycol.....	300ml
Anhydrous Ethanol.....	50ml
Polyethylene Glycol 400 adds up to.....	1000ml

#### PRODUCT DESCRIPTION

**Florcol 30% Oral Solution** is a new and highly effective antimicrobial. It is described as the 3<sup>rd</sup> generation of chloramphenicol with the enhanced spectrum of activity but minus the notorious side effects of the chloramphenicols. Florcol 30% Oral Solution is a colorless to light yellow clear liquid with Florfenicol 30% w/v. Florcol 30% Oral Solution contains not less than 95% w/v and not more than 105.0% w/v of the label stated amount of florfenicol. Florcol 30% Oral Solution is to be stored in an air-tight container and protected from light.

#### PHARMACODYNAMICS:

Florfenicol acts by interfering with bacterial protein synthesis. It binds reversibly to the 50-S subunit of the 70-S ribosome in the presence of Ca and Mg ions and so impairs peptidyl transferase activity. Florfenicol is mainly bacteriostatic but in high concentration it may be bactericidal for some species. Its range of activity is similar to that of tetracycline and includes Gram-positive and Gram-negative bacteria, *Rickettsia* spp., and *Chlamydiaceae*. The sensitivities of *Salmonella typhi*, *Haemophilus influenzae*, and *Bacteroides fragilis* to chloramphenicol have dictated the principal indications for its use. Florfenicol is active when given orally and, unlike most other antibacterials, it diffuses into the CSF even when the meninges are not inflamed. The majority of a dose is inactivated in the liver, only a small proportion appearing unchanged in the urine. **Florfenicol** belongs to a new generation of veterinary medicine. Comparing to Chloramphenicol and Thiamphenicol, Florfenicol has a broader anti-microbial spectrum, stronger in activity, excellent absorption and penetration to the site of infection, no record of resistance, low toxicity, no risk of aplastic anemia. Florfenicol has greater advantage than many commonly used antibiotics. It is effective in treating bacterial infection that is resistant towards Chloramphenicol, Thiamphenicol, Tetracycline, Oxytetracycline, Amoxicillin and Quinolones.

#### PHARMACOKINETICS:

Florfenicol is absorbed from the GIT. Approximately 40-60% is bound to the plasma protein albumen. The unbound fraction diffuses easily into all the tissues. High





concentrations of Florfenicol are bound in the liver and kidneys. Concentration of about 50% of the plasma concentrations are reached in the cerebrospinal fluid and aqueous humors. Florfenicol is mainly excreted by metabolism in the liver, especially by conjugation with glucuronic acid. Excretion of inactive metabolites is mainly via the kidneys and some from the bile. A small amount of Florfenicol could be found in the faeces, because of enterohepatic cycling.

**Florcol 30% Oral Solution** is the First-Choice drug for treating bacillosis in poultry and Actinobacillus pleuroneumoniae (App) in swine. **Florcol 30% Oral Solution** is also effective in treating many bacterial infections and especially E. coli, CCRD and Salmonellosis etc.

#### **Main Characteristics:**

1. Broad Spectrum of antibacterial action
2. Higher potency than many commonly used antibiotics
3. No record of resistance or cross-resistance
4. Fast acting and long acting
5. Able to penetrate blood-brain barrier
6. No harmful effect on humans and food consumption

**USAGE:** For use in infections caused by both Gram-positive and Gram-negative bacteria like Pasteurella multocida, Pasteurella haemolytica, Haemophilus parasuis, Actinobacillus pleuroneumoniae, Bordetella broachiseptics, Streptococcus, Staphylococcus, E. coli, Mycoplasma, Salmonella, Clostridium etc.

**DOSAGE:** By Oral Route

Poultry: 1ml per 5 litres of water or 100ml per 500 litres of water for 4-5 days

Calves: 0.5ml per 10Kg bodyweight for 5 to 7 days

#### **CONTRA/INDICATIONS/SAFETY DATA:**

Excessive use of Florfenicol can cause hypersensitivity.

Do not administer to animals with renal impairment.

Do not administer to animals with sensitivity towards chloramphenicols

Pregnant animals or lactating animals should be avoided

Do not administer while vaccination is given or narcotic is given

#### **WARNING AND PRECAUTION:**

1. Reduce dose in renal impairment if needed
2. Do not exceed the stated dose or dosage period



3. Avoid concomitant administration with other antibiotics and especially the quinolones.

### **INTERACTIONS WITH OTHER MEDICATIONS**

Florfenicol may delay the absorption of a number of co-administered drugs which are metabolised and inactivated in the liver such as pentobarbital, codeine, non steroidal anti-inflammatory drugs and the coumarin derivatives. Florfenicol may also interact with iron preparations, folic acid and vitamin B12, narcotic drugs and a number of antibiotics like Flumequine, cephalosporins and aminoglycosides. Florfenicol may be used with Bromhexine and Colistin which could enhance its antimicrobial activity.

### **PREGNANCY AND LACTATION**

Avoid usage of Florcol 30% Oral Solution in pregnant and lactating animals. Not to be used for layers laying eggs for human consumption.

### **SIDE EFFECTS:**

Hypersensitivity, stomatitis and GIT disturbances may occur in some cases. This is as a result of atrophy of the intestinal villi. Prolonged and excessive overdose treatment may lead to bone marrow suppression and immuno suppression.

### **SYMPTOMS AND TREATMENT OF OVERDOSE**

A mild overdose will not have any significant or lasting problem. However, if excessive dose of Florcol 30% Oral Solution is given, it will affect the kidneys possibly causing poor kidney function or even kidney failure. The typical symptoms would include the usual side effects but more severely like hypersensitivity rashes, nausea, vomiting and diarrhea. In the event of recent acute overdose, the stomach should be emptied by inducing vomiting or by gastric lavage, and the animals carefully observed and given symptomatic and supportive treatment. Usage of diuretics could be useful. Dialysis, if necessary, could be used as the last resort.

### **WITHDRAWAL PERIOD:**

7 Days prior to slaughter

10 days prior to layers laying eggs for human consumption.

### **STORAGE**

Store in an airtight container and protected from light.

### **PROPOSED SHELF LIFE:**

2 years as packaged for sale

Manufactured by:

**Vetpharm Lab (S) Pte Ltd**

27, Tuas Ave 13, #01-25

Singapore 638993





**Distributor:**

ADVANCE ANIMAL SCIENCE COMPANY LTD  
149-A, DIT EXTENSION ROAD  
MOTIJHEEL  
DHAKA 1000. BANGLADESH

Florfenicol

**Drug Nomenclature**

*Date of monograph revision:* 11-Jul-1997; 18-Aug-1998; 04-Apr-2000; 10-Aug-2001; 05-Nov-2002; 25-Jul-2006

*Synonyms:* Florfenicol; Florfenicolum; Florfenikol; Florfenikoli; Sch-25298

*BAN:* Florfenicol

*USAN:* Florfenicol

*INN:* Florfenicol [rINN (en)]

*INN:* Florfenicol [rINN (es)]

*INN:* Florfénicol [rINN (fr)]

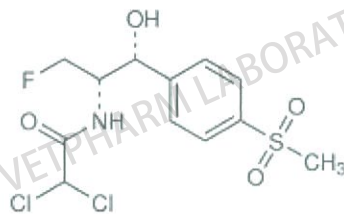
*INN:* Florfenicolum [rINN (la)]

*INN:* Флорфеникол [rINN (ru)]

*Chemical name:* 2,2-Dichloro-N-[( $\alpha$ S, $\beta$ R)- $\alpha$ (fluoromethyl)- $\beta$ -hydroxy-4-methanesulfonylphenethyl]acetamide

*Molecular formula:* C<sub>12</sub>H<sub>14</sub>Cl<sub>2</sub>FNO<sub>4</sub>S = 358.2

*CAS:* 76639-94-6



Chemical Structure of Florfenicol

**Drug Profile**

Florfenicol, a fluorinated analogue of chloramphenicol, is an antibacterial used in veterinary medicine.

