

# ANCOFLOR 300

## COMPOSITION

Florfenicol 300 mg – Excipients q.s.p. 1 ml.

## PHARMACOLOGICAL PROPERTIES

Florfenicol is a synthetic broad spectrum antibiotic effective against most Gram-positive and Gram-negative bacteria isolated from domestic animals. Florfenicol acts by inhibiting protein synthesis at the ribosomal level and is bacteriostatic. However, bactericidal activity has been demonstrated in vitro against most common porcine bacterial pathogens involved in respiratory disease: *Actinobacillus pleuropneumonia* and *Pasteurella multocida*.

Acquired resistance to florfenicol is mediated by efflux pump resistance associated with a flo gene. Cross resistance with chloramphenicol can occur.

After intramuscular administration of the recommended dose of 15 mg/kg, maximum serum concentration of 2.48 µg/ml is reached after 2.0 hours and the concentrations deplete with a terminal half-life of 14.9 hours. Serum concentrations drop below 1 µg/ml, the MIC90 for the target porcine pathogens, 12-24 hours following IM administration. Florfenicol concentrations achieved in lung tissue reflect plasma concentration, with a lung: plasma concentration ratio of approximately 1. After administration to pigs by the intramuscular route, florfenicol is rapidly excreted, primarily in urine. The florfenicol is extensively metabolised.

## TARGET SPECIES

Pigs.

## INDICATIONS

Diseases caused by florfenicol susceptible bacteria.

Pigs: Treatment of acute outbreaks of swine respiratory disease caused by strains of *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* susceptible to florfenicol.

## CONTRA-INDICATIONS

Do not use in boars intended for breeding purposes.

Do not use in piglets of less than 2 kg.

Do not administer to animals with known hyper-sensitivity to florfenicol or to any of the excipients.

Do not administer intravenously.

## DOSAGE AND MODE OF ADMINISTRATION

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing. The vial cannot be broached more than 25 times.

I.M.injection of 15 mg/kg body weight (1 ml/20 kg) into the neck muscle twice 48 hour apart.

The volume administered per injection site should not exceed 3 ml. Subsequent injections must be given at different sites.

It is recommended to treat animals in the early stages of disease and to evaluate the response to treatment within 48 hours after the second injection. If clinical signs of respiratory disease persist 48 hours after the last injection, treatment should be changed using another formulation or another antibiotic and continued until clinical signs have resolved.

### **UNDESIRABLE EFFECTS**

Commonly observed adverse effects are transient diarrhoea and/or peri-anal and rectal erythema/oedema which may affect 50% of the animals. These effects can be observed for one week.

Transient swelling lasting up to 5 days may be observed at the site of injection.

Inflammatory lesions at the injection site may be seen up to 28 days.

Under field conditions, approximately 30% of treated pigs may present with pyrexia (40°C) associated with either moderate depression or moderate dyspnoea a week or more after administration of the second dose.

### **SPECIAL PRECAUTIONS FOR USE AND WARNINGS**

The product should be used in conjunction with susceptibility testing and take into account official and local antimicrobial policies.

The stopper must be cleaned before removing each dose.

Use a dry, sterile syringe and needle.

### **WITHDRAWAL PERIOD**

Meat and offal: 18 days.

### **PACK SIZE**

Glass vials of 100 and 250 ml.