# Spirachlor
## POWDER

For Veterinary Use Only

**Composition:**
Each gram contains:
Spiramycin Adipate .....25mg
Chlortetracycline HCl .....75mg

**Indications:**
Spirachlor powder is indicated for the treatment of respiratory and gastrointestinal tract diseases caused by staphylococcus spp.streptococcus spp.mycoplasma, pasteurella, clostridium,escherichia coli and salmonella spp.

**Pharmacology:**
Chlortetracycline is a member of the tetracycline group of antibiotics.Tetracyclines generally act as bacteriostatic antibiotics and inhibit protein synthesis by reversibly binding to 30S ribosomal subunits of susceptible microorganisms, thereby preventing binding to those ribosomes of aminoacyl transfer-RNA.Tetracyclines also are believed to reversibly bind to 50S ribosomes and additionally alter cytoplasmic membrane permeability in susceptible organisms. In high concentrations, tetracyclines can also inhibit protein synthesis of mammalian cells.Spiramycin is a macrolide antibiotic and acts by binding to the 50S subunit of the bacterial ribosome. Its action is bacteriostatic but on highly sensitive strains it acts as bactericidal. Spiramycin metabolism has not been well studied,however spiramycin is thought to be metabolized in the liver to active metabolites.

**Pharmacokinetics:**
Chlortetracycline is readily absorbed after oral administration to fasting animals.
Bioavailabilities are approximately 60-80%. The presence of food or dairy products can significantly reduce the amount of tetracycline absorbed, with reductions of 50% or more possible.Tetracyclines as a class, are widely distributed to heart, kidney, lungs, muscle, pleural fluid, bronchial secretions, sputum, bile, saliva, urine, synovial fluid, ascitic fluid, and aqueous andvitreous humor. Only small quantities of tetracyclines are distributed to the CSF, and therapeutic levels may not be achievable. Tetracyclines cross the placenta, enter fetal circulation and are distributed into milk. The volume of distribution of tetracycline is approximately 1.2 - 1.3 L/kg in small animals. The amount of plasma protein binding is about 20 - 67% for tetracyclines. Tetracyclines are eliminated unchanged primarily via glomerular filtration. Animals with impaired renal function can have prolonged elimination half-lives and may accumulate the drug with repeated dosing. These drugs apparently are not metabolized, but are excreted into the GI tract via both biliary and nonbiliary routes and may become inactive after chelation with fecal materials.

**Interactions:**
When orally administered, tetracyclines can chelate **divalent or trivalent cations** which can decrease the absorption of the tetracycline or the other drug if it contains these cations. Oral antacids, saline cathartics or other GI products containing aluminum, calcium, magnesium, zinc or bismuth cations are most commonly associated with this interaction. It is recommended that all oral tetracyclines be given at least 1-2 hours before or after the cations containing product. **Oral iron products** are also associated with decreased tetracycline absorption, and administration of iron salts should preferably be given 3 hours before or 2 hours after the tetracycline dose. **Oral sodium bicarbonate, kaolin, pectin, or bismuth subsalicylate** may impair tetracycline absorption when given together orally. Tetracyclines may increase the bioavailability of digoxin in a small percentage of patients (human) and lead to **digoxin** toxicity. These effects may persist for months after discontinuation of the tetracycline.Tetracyclines may depress plasma prothrombin activity and patients on **anticoagulant** (e.g., **warfarin**) therapy may need dosage adjustment. Tetracyclines have been reported to increase the nephrotoxic effects of **methoxyflurane** and tetracycline HCl or oxytetracycline are not recommended to used with methoxyflurane. GI side effects may be increased if tetracyclines are administered concurrently with **theophylline** products. Tetracyclines have reportedly reduced **insulin** requirements in diabetic patients, but this interaction is yet to be confirmed with controlled studies. Oral neomycin should not be given concurrently with oral **penicillin VK** as malabsorption of the penicillin may occur.Oral neomycin with orally administered **digitalis preparations** (e.g., **digoxin**) may result in decreased
absorption of the digitalis. Separating the doses of the two medications may not
alleviate this effect. Oral neomycin may decrease the amount of **vitamin K** absorbed from the gut; this may have ramifications for patients receiving **oral anticoagulants. Methotrexate** absorption may be reduced by oral neomycin. Although only minimal amounts of neomycin are absorbed after oral administration, the concurrent use of other **ototoxic or nephrotoxic drugs** with neomycin should be done with caution. Spiramycin is known to interact with other drugs like Astemizole, Carbidopa, Cimentidine. These interactions are sometimes beneficial and sometimes may pose threats to life.

**Toxicology:**
Chronic tetracycline overdoses may lead to drug accumulation and nephrotoxicity. High oral doses given to ruminants, can cause ruminal microflora depression and ruminoreticular stasis.Rarely, oral tetracycline may cause ototoxicity, nephrotoxicity, severe diarrhea and intestinal malabsorption.

**Mechanism of action:**
The mechanism of action of spiramycin is not clear; however, it is thought to reversibly bind to the 50S subunit of bacterial ribosomes, resulting in blockage of the transpeptidation or translocation reactions, inhibiting protein synthesis and subsequent cell growth. It is primarily bacteriostatic, but may be bactericidal against more sensitive strains when used in high concentrations. Spiramycin also accumulates in high concentrations in the bacterial cell. Unlike erythromycin, spiramycin does not produce gastrointestinal motility stimulation.

**Absorption:**
The absorption of spiramycin is incomplete, with an oral bioavailability of 33 to 39% (range, 10 to 69%). The rate of absorption is slower than that of erythromycin and is thought to be due to the high pKa (7.9) of spiramycin, suggesting a high degree of ionization in the acidic stomach. Studies have shown that administration with food reduces bioavailability by approximately 50% and delays the time to peak serum concentration.
**Distribution:**
Spiramycin is highly concentrated in tissues, such as the lungs, bronchi, tonsils, sinuses, and female pelvic tissues. These high tissue concentrations persist long after serum concentrations have fallen to low levels. Peak concentrations in the saliva are 1.3 to 4.8 times greater than those found in the serum. Spiramycin crosses the placenta and is distributed into milk, however, fetal blood concentrations are only 50% of the maternal serum concentrations. Concentrations in the placenta are up to 5 times higher than the corresponding serum concentration. High concentrations are also found in the bile, polymorphonuclear leukocytes, and macrophages. Biliary concentrations are 15 to 40 times higher than the serum concentration. Spiramycin does not cross the blood-brain barrier.

**Protein binding:** Low (10 to 25%).
**Time to peak concentration:**
Oral—3 to 4 hours.

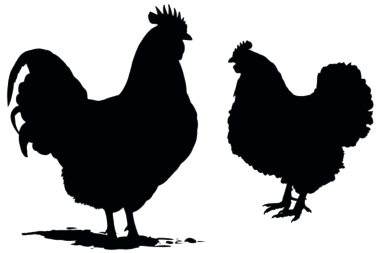
**Peak serum concentration:**
Oral: Approximately 1 mcg/ml after a 1-gram dose.
1.6 to 3.1 mcg/ml after a 2-gram dose.

**Elimination:**
Fecal,biliary elimination is substantial, with over 80% of an administered dose excreted in the bile, enterohepatic recycling may occur. Urinary excretion accounts for only 4 to 14% of an administered dose.

**Dosage and administration:**
Administer the following dose in drinking water.
1gm in l liter of water for 3-5 days.

**Warnings:**
1.Protect from light and heat.
2.Store between 15- 25°C in cool and dry place.
3.Consult the veterinarian before use.

**Innovator's Specs.**



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