SULFATRIN INPEL

ANTIBIOTIC

ORAL SOLUTION

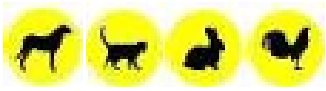
Health Registration No.: 2B1-7899-AGROCALIDAD

Formula:

Each 100 mL contains:

Trimethoprim	1.60 g
Sulfamethoxazole	8.00 g
Tylosin	2.00 g
Excipients q.s.	100.0 ml

SPECIES AND DOSAGE:



DOSAGE AND ADMINISTRATION

Poultry

Age (Weeks)	mL Sulfatrin in 1 L of Water	Number of Animals
1	3.5 mL	36
2	3 mL	15
3	3 mL	9
4	3.5 mL	6
5	4 mL	5
6	5 mL	4

Reference dose: 50–100 mg/kg sulfamethoxazole + trimethoprim

Canines: 3 mL per 10 kg of body weight
Felines and Rabbits: 1 mL per 3 kg of body weight

Reference dose: Sulf + Trimethoprim
Canines and felines: 30 mg/kg. Rabbits: 15–30 mg/kg
Tylosin: Canines and felines: 7 mg/kg. Rabbits: 10 mg/kg

ROUTE OF ADMINISTRATION: Oral.
Administer every 12 hours for 5 consecutive days, unless otherwise directed by the veterinarian.

INDICATIONS:

Infections of the upper and lower respiratory tracts, bronchitis, pneumonia, kidney and urinary tract infections, gastrointestinal infections.

ROUTE OF ADMINISTRATION: Oral.

PHARMACOKINETICS:

SULFAMETHOXAZOLE TRIMETHOPRIM
This combination is efficiently absorbed in the gastrointestinal tract, with peak levels reached at 4 hours. Its half-life has not been determined in animals, except in chickens, in which the value is 8.77 hours with Cmax of 146 µg/mL, Tmax of 2 hours, and Vd AUC: 0.312 L/kg. In humans, the half-life (T½B) is 10 hours. It binds to plasma proteins at 65% and is eliminated by the kidneys at a rate of 25–50% within 24 hours. The trimethoprim/sulfamethoxazole combination is well absorbed when administered orally and reaches peak levels 1–4 hours after dosing; the drug is absorbed more slowly following subcutaneous injection. It is well distributed throughout the body. When the meninges are inflamed, the drugs enter the cerebrospinal fluid at a concentration equivalent to 50% of that found in serum. Both drugs cross the placenta and are excreted into milk. The volume of distribution for trimethoprim is 1.49 L/kg in dogs and 0.59–1.51 L/kg in horses. The combination is excreted unchanged in the urine via glomerular filtration and tubular secretion and is metabolized by the liver.

TYLOSIN
Tylosin tartrate is well absorbed from the gastrointestinal tract, primarily from the intestine. The phosphate salt is less well absorbed following administration Oral. Tylosin base, when administered subcutaneously (SC) or intramuscularly (IM), is rapidly absorbed. Like erythromycin, tylosin is well distributed throughout the body after systemic absorption, with the exception of penetration into the cerebrospinal fluid. The volume of distribution of tylosin is 1.7 L/kg in small animals and 1 2.3 L/kg in cattle. In lactating dairy cows, the milk-to plasma ratio is 1–5.4. Tylosin is excreted in urine and bile, apparently as an unchanged drug. The elimination half-life of tylosin is 54 minutes.

MECHANISM OF ACTION:

SULFAMETHOXAZOLE TRIMETHOPRIM
Sulfonamides alone are bacteriostatic, and trimethoprim is bactericidal; however, when used in combination, sulfa enhanced drugs are bactericidal. They sequentially inhibit enzymes in the folic acid pathway, preventing the synthesis of thymidine in bacteria. Sulfonamides block the conversion of para-aminobenzoic acid (PABA) to dihydrofolic acid, and trimethoprim blocks the conversion of dihydrofolic acid to tetrahydrofolic acid by inhibiting dihydrofolate reductase. The optimal in vitro ratio for the most susceptible bacteria is approximately 1:20 (trimethoprim: sulfa), but synergistic activity can occur at ratios ranging from 1:1 to 1:40. The serum concentration of trimethoprim is considered more important than the concentration of sulfa. For the most susceptible bacteria, the minimum inhibitory concentration for trimethoprim is above 0.5 µg/mL in most cases. Potentiated sulfa drugs have a fairly broad spectrum of activity. Gram-positive bacteria that are typically susceptible include Most streptococci, many strains of Staphylococcus, and Nocardia. In horses, approximately 30% of the tested strains of Streptococcus zooepidermicus are resistant to the trimethoprim/sulfa combination. Many

Gram negative microorganisms of the Enterobacteriaceae family are susceptible to enhanced sulfa compounds, but not Pseudomonas aeruginosa. Some protozoa (Pneumocystis carinii, coccidia, and Toxoplasma) are also inhibited by this combination. Enhanced sulfa compounds have been reported to have little activity against most anaerobes, but opinions on this vary.

TYLOSIN

Tylosin is thought to have the same mechanism of action as erythromycin (binding to the 50S ribosomal subunit and inhibition of protein synthesis) and exhibits a similar spectrum of activity. It is a bacteriostatic antibiotic. Tylosin may have immunomodulatory effects on cell mediated immunity. In dogs, it increases the concentration of enterococci (Enterococcus fecalis) in the jejunum. Enterococci are thought to have a probiotic effect.

PRECAUTIONS- WARNINGS-CONTRAINDICATIONS:

- Administer only to the indicated species.
- Keep out of the reach of children.
- Use the product before the expiration date printed on the label. Hypersensitivity to any of the ingredients. Do not use in newborns or pregnant females. Do not use in cases of renal and/or hepatic insufficiency. May cause dry conjunctivitis in small animals. During 10-day treatment courses, polyarthritis and fever may develop, which resolve upon discontinuation of therapy. Doberman Pinschers are particularly susceptible to adverse reactions, including severe skin reactions.

DRUG INTERACTIONS

Sulfonamides may interact with other drugs. They may increase the metabolism of cyclosporine, resulting in a decrease in plasma concentration.

ADVERSE REACTIONS

Dogs may be more sensitive to sulfonamides than other animals. The most significant adverse effect caused by sulfamethoxazole in dogs is keratoconjunctivitis sicca, which is not breed-specific and is believed to result from a direct effect of the nitrogen in the pyridine ring on the lacrimal cells. It occasionally causes erythema, petechiae, internal hemorrhages, and hematuria.

WITHDRAWAL

Poultry: 5 days.
Meat: 21–30 days.
Do not use in laying hens producing eggs for human consumption.

COMMERCIAL PRESENTATIONS

50-ml bottle