

Veterinary Package Insert

TP-SULTRIXIN 40/200MG/ML SOLUTION

PRODUCT DESCRIPTION

Light yellow to yellow colour liquid, which contains sulfadimethoxin sodium 200mg (equivalent to 186.8mg of sulfadimethoxin), Trimethoprim 40mg and propylene glycol 312mg (as preservative) in 1ml of solution.

PHARMACODYNAMICS & PHARMACOKINETICS

Sulfadimethoxine is a long acting sulphonamide with a very broad activity spectrum that also has anticcocidal properties. It is active against Gram-positive and Gram-negative bacteria and some protozoa such as coccidia.

Trimethoprim belongs to the diaminopyrimidine family. It is active against streptococci and most Gram-negative bacteria.

In combination, these two active ingredients are synergistic. Sulfadimethoxine is potentiated by a diaminopyrimidine, trimethoprim. The combination of these two active ingredients allows a sequential blocking of the biosynthesis of folic acid. These two substances act sequentially on the synthetic pathway of tetrahydrofolic acid: the sulfonamide by inhibiting the incorporation of para-aminobenzoic acid in folic acid, trimethoprim by specifically inhibiting microbial dihydrofolate reductase. The spectrum of theoretical activity extends to both Gram-positive (Staphylococcus, Listeria etc.) and Gram-negative germs (Escherichia coli, Salmonella, Proteus, Enterobacter, Bordetella etc.).

Sulfadimethoxine is considered a sulphonamide retardant with a longer persistence of plasma levels. Its binding to plasma proteins is important. The distribution is good in most tissues and organs.

Trimethoprim is rapidly absorbed after oral administration. It is widely distributed in the body.

Both active ingredients are partially metabolized in the liver. Their elimination is essentially renal.

INDICATION

In poultry:

- Affections with germs sensitive to trimethoprim and sulfadimethoxine:
- Treatment and prevention of respiratory and digestive infections.
- Treatment and prevention of digestive coccidiosis.

TARGET SPECIES

Poultry.

RECOMMENDED DOSAGE AND ADMINISTRATION

To be administered in drinking water.

From 18.68 to 37.36 mg of sulfadimethoxine and from 4 to 8 mg of trimethoprim per kg of live weight per day, for 5 consecutive days, orally, i.e 1 to 2 ml of solution per 10 kg body weight and per day for 5 consecutive days, to be diluted in the drinking water according to the real consumption of the animals to respect the weight posology (in mg/kg).

CONTRAINDICATIONS

Do not use if you have a history of sulphonamide or trimethoprim allergy.
Do not use in animals with severe renal or hepatic impairment.

WARNINGS & PRECAUTIONS.

Special warnings for each target species

Give plenty of water to the treated animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Handle this product with the recommended precautions to avoid exposure: Safety glasses and gloves are recommended. Avoid contact with skin and eyes.

In case of emergence, after exposure to the product, symptoms such as rash, consult a doctor and show this warning. Swelling of the face, lips or eyelids or breathing difficulties are more serious symptoms and require urgent medical attention.

Avoid handling this product if you have a history of allergy to trimethoprim or sulfonamides.

INTERACTIONS WITH OTHER MEDICATIONS

None known.

PREGNANCY AND LACTATION

Teratogenic and foetotoxic effects have been observed in laboratory animals at doses above the recommended therapeutic doses.

Use of the product during pregnancy and lactation is contraindicated.

ADVERSE EFFECTS

None known.

OVERDOSE & TREATMENT

None known.

WITHDRAWAL PERIOD

Meat and offal: Poultry: 6 day

Eggs: In the absence of a waiting time for eggs not to be used in laying poultry producing eggs for consumption (4 weeks before and during the start of egg laying).

MAXIMUM RESIDUAL LIMIT (MRL)

Substance / Drug Definition of residues in which MRL was set	Food	Maximum Residue Limits (MRLs) in food µg/kg
Trimethoprim	Edible offal, muscle (mammalian and chicken), egg (chicken)	50
Sulfadimethoxine	Edible offal (chicken and mammalian), muscle (chicken and mammalian)	100

STORAGE CONDITION

Store in a dry, cool place and avoid direct sunlight.
It should be store at room temperature (30°C or below.)

SHELF LIFE

2 years.

After 1st opening, reconstitution or dilution, use within 24 hours.

PACKING

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THYE PHARMA SDN. BHD.

(manufacturer & product registration holder)

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