

Veterinary Package Insert

TP-HITRIM 40/200MG/ML SOLUTION

PRODUCT DESCRIPTION

Light yellow to yellow colour liquid, which contains sulfamethoxazol 200mg, Trimethoprim 40mg in 1ml of solution.

PHARMACODYNAMICS & PHARMACOKINETICS

In vitro trimethoprim is generally bacteriostatic and has a broad spectrum of activity against both gram-positive and gram-negative bacteria. A synergistic and bactericidal effect occurs when trimethoprim is combined with sulfamethoxazole, because trimethoprim and sulfamethoxazole inhibit sequential steps in the synthesis of tetrahydrofolic acid, an essential metabolic cofactor in bacterial synthesis of purine and, subsequently, DNA.

Following oral administration both active ingredients are rapidly absorbed from the gut.

High trimethoprim concentrations are found in the kidneys, the liver and the lungs. With the exception of the kidneys, sulfamethoxazole concentrations in the tissues are significantly lower than in the plasma. Protein binding for trimethoprim and sulfamethoxazole is not very high.

The drugs are primarily excreted through the kidneys (both actively and passively), but elimination also occurs through the faeces. Elimination is relatively fast both in poultry and pigs. Plasma elimination half-life for trimethoprim in poultry is less than 1 hour and that of sulfamethoxazole, approximately 1.5 hours. In pigs, elimination half-life for both substances is approximately 2.5 hours. Within 48 hours after the last medication trimethoprim, sulfamethoxazole and their metabolites are undetectable in urine and faeces.

INDICATION

Pigs: Treatment and metaphylaxis of respiratory infections caused by Actinobacillus pleuropneumoniae susceptible to trimethoprim and sulfamethoxazole where the disease has been diagnosed in the herd.

Broilers: Treatment and methaphylaxis of respiratory infections caused by Escherichia coli susceptible to trimethoprim and sulfamethoxazole where the disease has been diagnosed in the flock.

TARGET SPECIES

Pigs and chickens (broilers).

RECOMMENDED DOSAGE AND ADMINISTRATION

Route of administration: in drinking water use. The product can be added directly to the drinking water to prepare a therapeutic solution at the calculated concentration, but can also be used in a concentrated stock solution by adding 100 ml of veterinary product per litre water and diluting this further if required. Do not use this veterinary medicinal product undiluted or in higher concentrated stock solutions.

Pigs: 25 mg TMPS per kg bodyweight per day for 3-4 days, corresponding to 0.5ml of veterinary product per 4,8 kg bodyweight per day. This corresponds to approximately 0.5litre of veterinary product in 500 L drinking water.

Based on the recommended dose, daily water consumption, and the number and weight of the pigs to be treated, the exact daily amount of the veterinary product can be calculated according to the following formula:

Mean body weight (kg)
of pigs to be treated

=

xx / 2 ml veterinary
product per l
drinking water

Mean daily water consumption
(l) per pig x 4.8

Broilers: 33 mg TMPS per kg bodyweight per day for 3-4 days, corresponding to 0.5ml of veterinary product per 3,64 kg bodyweight per day. This corresponds to approximately 0.5litre of veterinary product in 750 L drinking water.

Based on the recommended dose, daily water consumption, and the number and weight of the birds to be treated, the exact daily amount of the veterinary product can be calculated according to the following formula:

Mean body weight (kg)
of broilers to be treated

=

xx / 2 ml veterinary
product per l
drinking water

Mean daily water consumption
(l) per pig x 3.64

CONTRAINDICATIONS

Do not use in animals suffering from severe liver or kidney disease, oliguria or anuria.

Do not use in animals with impaired haematopoietic systems.

Do not use in case of known hypersensitivity to sulfonamides or trimethoprim or to any of the excipients.

WARNINGS & PRECAUTIONS.

I.) Special warnings for each target species

Severely diseased animals can have a decreased appetite and water consumption. If necessary the concentration of the product in the drinking water should be adjusted to make sure that the recommended dosage is being consumed. However if the concentration of the product is increased too much, the intake of the medicated drinking water decreases for palatability reasons. Therefore water intake should be monitored regularly, especially in broilers.

In case of insufficient uptake of water, pigs should be treated parenterally.

II.) Special precautions for use

Special precautions for use in animals

Official and local antimicrobial policies should be taken into account when the product is used.

Due to the likely variability (time, geographical) in susceptibility of bacteria for potentiated sulphonamides, occurrence of resistance of bacteria may differ from country to country and even from farm to farm, and therefore bacteriological sampling and susceptibility testing are recommended. Use of the product should be based on culture and sensitivity of micro-organisms from diseased cases on farm or from recent previous experience on the farm. Use of the product deviating from the instructions given here may increase the prevalence of bacteria resistant to sulfamethoxazole and trimethoprim and may also decrease the effectiveness of combinations of trimethoprim with other sulphonamides due to the potential for cross resistance.

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

This product contains sulfamethoxazole, which can cause allergic reactions in some people. People with known hypersensitivity (allergy) to sulphonamides or trimethoprim should avoid contact with the veterinary medicinal product.

During preparation and administration of the medicated drinking water, skin contact with the drug should be avoided. Therefore it is recommended to wear impermeable gloves e.g. rubber or latex when applying the product. Do not handle this product if you know you are allergic to trimethoprim or sulphonamides.

Do not smoke, drink or eat when handling the product.

If you develop symptoms following exposure to the product such as skin rash, you should seek medical advice and show the present warning to the doctor. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

This product can cause eye-irritation. Always wear protective glasses when mixing the product with drinking water. In the event of eye contact, rinse the eye with copious amounts of clean water and if irritation occurs, seek medical attention. In the event of accidental ingestion, seek medical advice. Wash hands and contaminated skin immediately after handling the product.

INTERACTIONS WITH OTHER MEDICATIONS

Do not combine with other veterinary medicinal products.

PREGNANCY AND LACTATION

Laboratory studies in rats conducted with trimethoprim have shown evidence of teratogenicity at higher doses than recommended therapeutic ones. The safety of the product during pregnancy and lactation has not been established in sows. The use of the product is not recommended in sows during pregnancy and lactation.

ADVERSE EFFECTS

A diminished water intake in chickens may occur occasionally.

Hypersensitivity reactions can occur rarely (more than 1 but less than 10 animals in 10,000 animals treated).

OVERDOSE & TREATMENT

In pigs, a 2 ½ fold overdose induces no adverse reactions.

In chicken an acute overdose will not occur because the birds will be reluctant to drink the strongly concentrated drinking water (too bitter taste if above 2 litres of the veterinary medicinal product per 1000 litre drinking water). Chronic overdose in chicken will result in a strongly diminished water- and feed intake and retarded growth.

WITHDRAWAL PERIOD

Meat and offal: Pigs: 5 days
Broilers: 6 days

Eggs: Not for use in birds producing or intended to produce eggs for human consumption.

MAXIMUM RESIDUAL LIMIT (MRL)

Substance / Drug Definition of residues in which MRL was set	Food	Maximum Residue Limits (MRLs) µg/kg
Trimethoprim	Edible offal, muscle (mammalian and chicken), egg (chicken)	50
Sulfamethoxazole	Muscle, liver, fat and kidney (all food producing species)	100

STORAGE CONDITION

Store below 30°C. Protect from direct sunlight.

SHELF LIFE

2 years.

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

PACKING

1 L

THYE PHARMA SDN. BHD.

(manufacturer & product registration holder)

No.2 Lorong Industri Ringan Permatang

Tinggi 8,

Kawasan Industri Ringan Permatang Tinggi,

14000 Bukit Mertajam,

Pulau Pinang.

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