Veterinary Package Insert

LS-SULFACHLO 125/625 MG/G WATER SOLUBLE POWDER

PRODUCT DESCRIPTION
Beige to light brown colour powder, which contains 625mg of sulfachloropyridazine sodium (580.2mg of sulfachloropyridazine) and 125mg of trimethoprim per gram in sachet.

PHARMACODYNAMICS & PHARMACOKINETICS
The antibacterial action of the veterinary medicinal product is based on a double sequential inhibition of the microbial synthesis of tetrahydrofolic acid. Trimethoprim is an antibacterial diaminopyrimidine derivative which shows a bactericidal and synergistic activity with sulfonamides.

Sulfachloropyridazine is an antibacterial sulfonamide that works by preventing bacterial multiplication. The combination of the two active ingredients has a synergistic effect and this has a beneficial effect on the dosage (reduction of the doses of the active ingredients), the bactericidal effect and the broadening of the spectrum of action.

In addition, the development of bacterial resistance is slowed down.

The veterinary medicinal product, administered at a dose of 200 mg/kg body weight, is effective in chickens against respiratory and septic infections of "wild type" E. coli and septic infections of P. multocida and S. aureus.

Resistance develops slowly through transferable elements and as a result of chromosomal mutation according to one or more of the following mechanisms:

- permeability barrier and/or efflux pumps
- naturally insensitive target enzymes
- controllable changes in the target enzyme.
- mutational or recombinational changes in the target enzyme
- acquired resistance by target enzymes resistant to the veterinary medicinal product.

The pharmacokinetic parameters in chickens after a single administration of the veterinary medicinal product at the recommended daily dose are summarised in the following table, as well as the steady state plasma concentrations (Css) after continuous medication via the drinking water.

Significantly higher plasma concentrations are achieved with sulfachloropyridazine.

	Trimethoprim	Sulfachloropyridazine
C_{max} (µg/ml)	0,52	18,65
AUC_{24h} .u/ml)	2,14	103,4
T_{max} (u)	1,55	1,32
$T_{1/2el}$ (u)	1,41	2,60
Css (µg/ml)	0,089	4,31

Plasma protein binding is 24.1% for trimethoprim and 35.1% for sulfachloropyridazine. This gives an effective Css (steady state) of 0.068 µg/ml for trimethoprim and 2.797 µg/ml for sulfachloropyridazine. Both active components are absorbed at approximately the same rate and excreted relatively quickly.

INDICATION
Treatment of infections caused by germs susceptible to trimethoprim/sulfachloropyridazine, taking into account the ability of the antibiotic to reach the site of infection in effective concentrations.

TARGETED SPECIES
Chicken (non-egg laying).

RECOMMENDED DOSAGE AND ADMINISTRATION
For oral administration via drinking water

Richtdosis: 32 mg of product per kg body weight per day (= 24 mg total active ingredient). A higher dose may be indicated, especially in the case of both primary and secondary E. coli infections.

Method of administration:
Chickens: mix product in the drinking water for 3 to 6 days.

$$\ldots \text{ mg product/kg body weight/day} * \frac{\text{x average body weight (kg) of the birds to be treated}}{\text{average daily water intake (L) per animal}}$$

= …mg product per L drink water

24mg TMP + sulph/kg body weight is equivalent to 32 mg veterinary medicinal product/kg body weight.

CONTRAINDICATIONS
Do not use in animals that are hypersensitive or have liver or kidney disease.

Do not use in animals with impaired hematopoietic function.

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

WARNINGS & PRECAUTIONS.
Special warnings for each animal species for which the veterinary medicinal product is intended

Avoid underdosing. Sick animals can drink less water than normal. If the animals can be isolated, the concentration of the veterinary medicinal product in the water can be increased proportionately.

Water intake should be monitored regularly, especially in broiler chickens.

Special precautions for use in animals
Due to the variable sensitivity (temporal, geographical) of bacteria to potentiated sulfonamides, resistance of bacteria can differ from country to country and even from farm to farm. Bacteriological samples and susceptibility testing are therefore recommended. The veterinary medicinal product should be used on the basis of the culture and susceptibility of micro-organisms in sick farm animals or on the basis of recent previous experience on the farm.

If the veterinary medicinal product is used differently than specified in the product leaflet, it may increase the prevalence of bacteria resistant to sulfachloropyridazine and trimethoprim and reduce the effectiveness of combinations of trimethoprim with other sulfonamides due to possible cross-resistance. Official and local antimicrobial policies should be respected when using the veterinary medicinal product.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Sulfonamides may cause hypersensitivity reactions (allergy) after injection, inhalation, ingestion or contact with the skin. Hypersensitivity to sulfonamides may lead to cross-reactions with other antibiotics. Allergic reactions caused by these substances can be serious in some cases.

Avoid contact with this veterinary medicinal product if you are sensitive to sulfonamides.

If symptoms occur after exposure, such as rash, consult a doctor and show this warning to the doctor.

Wear impermeable gloves, e.g. rubber or latex, and protective glasses when handling the veterinary medicinal product.

In case of eye contact, rinse the eye thoroughly with clean water and, if irritation occurs, seek medical attention.

In case of accidental ingestion, consult a doctor.

Wash your hands and contaminated skin immediately after using the veterinary medicinal product.

INTERACTIONS WITH OTHER MEDICATIONS

Do not combine with other veterinary medicinal products.

PREGNANCY AND LACTATION
The safety of the veterinary medicinal product has not been established during lay.

ADVERSE EFFECTS
Sulfonamides may rarely affect renal function (crystalluria, hematuria, urinary blockage) and hematopoiesis (thrombocytopenia, anemia).

The frequency of side effects is defined as follows:

- Very common (more than 1 in 10 treated animals exhibiting adverse reaction(s))
- Common (more than 1 but less than 10 out of 100 animals treated)
- Uncommon (more than 1 but less than 10 out of 1,000 animals treated)
- Rare (more than 1 but less than 10 out of 10,000 animals treated)
- Very rare (less than 1 in 10,000 animals treated, including isolated reports)

OVERDOSE & TREATMENT
The target animals tolerate doses that are at least 5 times higher than the recommended dose administered for at least 3 times the maximum recommended treatment period, without showing any adverse effect.

WITHDRAWAL PERIOD
Chicken Meat: 7 days

It should not be used in chickens producing eggs for human consumption.

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
Sulphonamide	Muscle, liver, kidney, fat (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
1kg

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(product registration holder)
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