TYVALONE 625MG/G WATER SOLUBLE POWDER

FOR ANIMAL USE ONLY

PRODUCT NAME

TYVALONE 625MG/G WATER SOLUBLE POWDER

NAME AND STRENGTH OF ACTIVE INGREDIENT

Each g contains Tylvalosin 625 mg (equivalent to Tylvalosin Tartrate 715 mg)

PRODUCT DESCRIPTION

A white or almost white powder.

PHARMACODYNAMIC PROPERTIES

Tylvalosin is a macrolide antibiotic. Macrolides are metabolites or derivatives of metabolites of soil organisms obtained by fermentation. They interfere with protein synthesis by reversibly binding to the 50S ribosome subunit. They are generally considered bacteriostatic. Tylvalosin has activity against pathogenic organisms isolated from a range of animal species, mainly Gram-positive organisms and mycoplasma but also some Gram-negative organisms. Macrolides (including tylvalosin) have been shown to have effects on the innate immune system, which may augment the direct effects of the antibiotic on the pathogen and aid the clinical situation.

Chicken: Tylvalosin has activity against the following mycoplasma species found in chicken: *Mycoplasma gallisepticum*. The minimal inhibitory concentration (MIC) of tylvalosin for *M. gallisepticum* ranges from 0.007 to 0.25 µg/ml.

PHARMACOKINETIC PROPERTIES

Tylvalosin tartrate is rapidly absorbed after oral administration of the veterinary medicinal product. Tylvalosin is widely distributed in tissues, with the highest concentrations found in the respiratory tissues, bile, intestinal mucosa, spleen, kidney and liver. Tylvalosin has been shown to concentrate in phagocytic cells and gut epithelial cells. Concentrations (up to 12 times) were achieved in the cells (intracellular), compared to the extracellular concentration. *In vivo* studies have shown tylvalosin to be present in higher concentrations in the mucous lining of the respiratory and gut tissues compared to the plasma. The major metabolite of tylvalosin is 3-acetyltylosin (3-AT), which is also microbiologically active. The terminal half-lives for the elimination of tylvalosin and its active metabolite 3-AT range from 1 to1.45 hours in the chicken. Six hours after treatment, the concentration of tylvalosin in the gastrointestinal tract mucosa has a mean concentration of 133 ng/g and in the gastrointestinal contents of 1,040 ng/g. The active metabolite 3-AT has a mean concentration of 57.9 ng/g and 441 ng/g, respectively.

INDICATIONS

Chickens :

Treatment and metaphylaxis of respiratory infections caused by *Mycoplasma gallisepticum* in chickens.

The presence of the disease in the flocks should be established before metaphylactic treatment. As an aid in reducing the development of clinical signs and mortality from respiratory disease in flocks, where infection in ovum with *Mycoplasma gallisepticum* is likely because the disease is known to exist in the parent generation.

TARGET SPECIES

Chickens.

ROUTE OF ADMINISTRATION

For use in drinking water.

DOSAGE

Chickens :

For treatment of respiratory disease associated with *Mycoplasma gallisepticum*:

The dose is 25 mg tylvalosin per kg bodyweight per day in drinking water for 3 consecutive days.

When used as an aid in reducing the development of clinical signs and mortality (where infection in ovum with *Mycoplasma gallisepticum* is likely):

The dose is 25 mg tylvalosin per kg bodyweight per day in drinking water for 3 consecutive days at 1 day old.

This is followed by a second treatment with 25 mg tylvalosin per kg bodyweight per day in drinking water for 3 consecutive days at the period of risk, i.e. at times of management stress such as administration of vaccines (typically when birds are 2–3 weeks old).

The product should be added to a volume of water that the chicken will consume in one day. No other source of drinking water should be available during the medication period.

Table 1. Summary of recommended dosage

Species	Indications	Tylvalosin per kg bodyweight per day	Product per kg bodyweight per day	Duration
Chickens	1. For treatment of respiratory disease associated with *Mycoplasma gallisepticum*	25 mg	40 mg	3 days
	2. When used as an aid in reducing the development of clinical signs and mortality (where infection in ovum with *Mycoplasma gallisepticum* is likely) a. First treatment at 1 day old b. Second treatment at the period of risk, i.e. at times of management stress such as administration of vaccines (typically when birds are 2–3 weeks old).	 25 mg 25 mg	 40 mg 40 mg	 3 days 3 days

Table 2. Dosage calculation

Species	Tylvalosin / kg bodyweight / day	Product / kg bodyweight / day	Amount of product used	Total weight of chickens treatable	Average bodyweight of chicken	Total number of chicken treatable
Chickens	25 mg	40 mg	40 g	40 g ÷ 40 mg/kg = **1,000 kg**	50 g	1,000 kg ÷ 50 g = **20,000** chickens
			160 g	160 g ÷ 40 mg/kg = **4,000 kg**	100 g	4,000 kg ÷ 100 g = **40,000** chickens
			200 g	200 g ÷ 40 mg/kg = **5,000 kg**	200 g	5,000 kg ÷ 200 g = **25,000** chickens
			400 g	400 g ÷ 40 mg/kg = **10.000 kg**	500 g	10,000 kg ÷ 500 g = **20,000** chickens
			1000 g	1000 g ÷40 mg/kg = **25.000 kg**	500 g	25,000 kg ÷ 500 g = **50,000** chickens

Direction of use:

When mixing the product directly into the drinking water system, the contents of the sachet should be sprinkled onto the surface of the water and mixed thoroughly until a clear solution is produced (usually within 3 minutes). When preparing a stock solution, the maximum concentration should be 40 g per 1,500 ml or 400 g of product per 15 litres water and it is necessary to mix the solution for 10 minutes. After this time, any remaining cloudiness will not affect efficacy of the product. Only a sufficient amount of medicated drinking water should be prepared to cover the daily requirements. Medicated drinking water should be replaced every 24 hours.

CONTRAINDICATIONS

None.

SPECIAL WARNINGS FOR EACH TARGET SPECIES

The strategy for Mycoplasma gallisepticum infection should include efforts to eliminate the pathogen from the parent generation. Infection with Mycoplasma gallisepticum is reduced but not eliminated at the recommended dose. Medication should only be used for short-term amelioration of clinical signs in breeder flocks whilst awaiting confirmation of diagnosis of Mycoplasma gallisepticum infection.

SPECIAL PRECAUTIONS FOR USE

Special precautions for use in animals: Good management and hygiene practices should be introduced to reduce the risk of re-infection. It is sound clinical practice to base treatment on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of target bacteria. Use of the veterinary medicinal product deviating from the instructions may increase the risk of development and selection of resistant bacteria and decrease the effectiveness of treatment with other macrolides due to potential for cross-resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals: Tylvalosin has been shown to cause hypersensitivity (allergic) reactions in laboratory animals; therefore, people with known hypersensitivity to tylvalosin should avoid contact with this product. When mixing the veterinary medicinal product and handling the medicated water, direct contact with eyes, skin and mucous membranes should be avoided. Personal protective equipment consisting of impervious gloves and a half-mask respirator or a nondisposable respirator with a filter should be worn when mixing the product. Wash contaminated skin. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

INTERACTIONS WITH OTHER MEDICAMENTS

None known

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USE DURING PREGNANCY, LACTATION AND LAY
Chickens: The product can be used in chickens laying eggs for human consumption and breeding birds producing eggs for hatching broiler stock or replacement layers.
ADVERSE EFFECTS
None known
OVERDOSE AND TREATMENT
No signs of intolerance have been observed in poultry species at up to 150 mg tylvalosin per kg bodyweight per day for 5 days.
WITHDRAWAL PERIODS
Chickens: Meat and offal: 2 days. Eggs: zero days.
SHELF LIFE
Shelf life as packaged for sale: 3 years. Shelf life after first opening : 24 hours. Shelf life after reconstitution : 24 hours.
ALLOWABLE MAXIMUM RESIDUAL LIMIT (MRL)
Chicken: Skin and fat, liver = 50 µg/kg, egg = 200 µg/kg (Commission Regulation (EU) No 37/2010)
STORAGE CONDITIONS
Store protected from sunlight and moisture in a cool place below 30 ºC. Keep out of reach of children. Jauhi ubat daripada kanak-kanak.
DISPOSAL OF CONTAINERS
Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
PACKAGING AVAILABLE
40 g, 160 g, 200 g, 400 g and 1000 g per aluminum sachet.
MANUFACTURER AND PRODUCT REGISTRATION HOLDER
Life Biopharma Sdn. Bhd. (company no. 546163-D)
No. 250-251, Jalan Industri Galla 13, Kawasan Perindustrian Galla, 70200 Seremban, Negeri Sembilan, Malaysia.
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