

Tylosina 66.8% w/w Water Soluble Powder (FOR VETERINARY USE ONLY)

COMPOSITION

Tylosin Tartrate 668g
(Tylosin activity.....607g)
Excipients q.s.....1000g

PRODUCT DESCRIPTION

It is a light yellow color powder.

PHARMACODYNAMICS

Tylosin is a macrolide antibiotic produced by a strain of *Streptomyces fradiae*. It exerts its antimicrobial effect by inhibiting protein synthesis of susceptible micro-organisms.

The tylosin spectrum of activity includes Gram-positive bacteria including *Clostridium perfringens* and some Gram-negative strains such as *Pasteurella* and *Mycoplasma* spp. at concentrations of 16µg/ml or less.

PHARMACOKINETICS

Absorption: Tylosin reaches maximal blood levels between 1 and 3 hours after an oral dose. Minimal or no blood levels remain 24 hours after an oral dose.

Distribution: After oral doses were given to pigs, tylosin was found in all tissues, between 30 minutes and two hours after administration, except for the brain and spinal cord.

Biotransformation and Elimination: It has been shown that most of the material which is excreted is to be found in the faeces and consists of tylosin (factor A), relomycin (factor D) and dihydrodesmycosin.

INDICATIONS

Chickens:

For the control of *Mycoplasma synoviae* airsacculitis and *Mycoplasma gallisepticum* S6 in chickens. In the field tylosin has also proved useful in reducing the level of infection following stress associated with live vaccination.

As an aid in the control of outbreaks of necrotic enteritis in chickens caused by *Clostridium perfringens*.

Pigs:

For the prevention and control of enzootic pneumonia, and scours caused by organisms (e.g. *Lawsonia intracellularis*) sensitive to tylosin

CONTRA-INDICATIONS

Do not leave or dispose of water containing tylosin tartrate where it may be accessible to either animals not under treatment or to wildlife.

Do not use in known cases of hypersensitivity to tylosin or other macrolides.

MODE OF ADMINISTRATION

Oral Administration through drinking water

RECOMMENDED DOSE:

Recommendations for use in chickens:

Tylosina Soluble is administered in the drinking water at a concentration of 0.82 g per litre.

As an aid in the control of outbreaks of necrotic enteritis caused by *Clostridium perfringens* in chickens use Tylosina in the drinking water for 5 days at a concentration of 0.25 g per litre water (150ppm), to provide 20-50 mg/kg bw, depending on the age and the water consumption of the birds.

Recommendations for use in pigs:

Tylosina Soluble is administered in the drinking water to provide 41.2 mg tylosin/kg bodyweight. This may normally be achieved by adding 0.412g per litre.

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid under-dosing.

Recommended programmes:

Chickens:

As an aid to mycoplasmosis prevention in Chicken

Class of Stock	Age	Tylosina Soluble at 0.82 g per litre
Broilers	0-3 days	57.7 g per 1000 birds
	4th week of life	57.7 g per 1000 birds
Layers and Replacement Pullets	0-3 days	57.7 g per 1000 birds
	4th week of life	57.7 g per 1000 birds
	9 th -12 th week	48 hours medication
	16 th – 20 th week	48 hours medication
Breeder	0-3 days	82.3g per 1000 birds
	4th week of life	131.8g per 1000 birds
	9 th , 12 th , 16 th , 20 th , 24 th , weeks of age	48 hours medication

For treatment of mycoplasmosis in Chickens

Class of Stock	Tylosina Soluble at 0.82 g per litre
Broilers	24-72 hours medication
Layers and Replacement Pullets	48-72 hours medication

As an aid in control of Necrotic Enteritis in Chickens

Class of Stock	Tylosina Soluble at 0.25 g per litre
Broilers	5 days
Layers and Replacement Pullets	5 days

Pigs:

A medicated solution of drinking water should generally be administered until 24 hours after scouring or respiratory symptom have ceased, normally 3-10 days. The diagnosis should be reviewed if there is no response after 5 days of medication.

Disease Treatment	Tylosina Soluble required	Water consumption (l) (appox.)
Enzootic pneumonia	41.2 g	100 litres
Illitis	8.2-16.5 g	100 litres

WARNING AND PRECAUTIONSSpecial precautions for use in animals

Use of the product should be based 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 the target bacteria.

Use of the product deviating from the instructions given may increase the prevalence of bacteria resistant to tylosin and may decrease the effectiveness of treatment with other macrolides, lincosamides and streptogramin B due to the potential for crossresistance.

Special precautions to be taken by the person administering the veterinary medicine

Tylosin may induce irritation. Macrolides, such as tylosin, may also cause hypersensitivity (allergy) following injection, inhalation, ingestion or contact with skin or eye. Hypersensitivity to tylosin may lead to cross reactions to other macrolides and vice versa. Allergic reactions to these substances may occasionally be serious and therefore direct contact should be avoided.

To avoid exposure during preparation of the medicated drinking water, wear overalls, safety glasses, impervious gloves and wear either a disposable half mask respirator. Wash hands after use.

In the event of accidental skin contact, wash thoroughly with soap and water. In case of accidental eye contact, flush the eyes with plenty of clean, running water.

Do not handle the product if you are allergic to ingredients in the product.

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

User Safety Warning:

Not for Human Use. Avoid contact with human skin. Exposure to tylosin may cause a rash.

Keep medicine out of reach of children / Jauhi daripada kanak-kanak

INTERACTION WITH OTHER MEDICAMENTS

None known

PREGNANCY AND LACTATION

No adverse effects to tylosin have been seen in fertility, multi-generation or teratology studies.

ADVERSE EFFECT

None known

OVERDOSE AND TREATMENT

There is no evidence of tylosin toxicity in animals, at dose rates of up to 1000 mg/kg.

WITHDRAWAL PERIODS

Withdrawal period(s): Animals must not be slaughtered for human consumption during treatment.

Species	Indications	Treatment Duration (days)	Dose	Meat Withdrawal Period (days)	Egg Withdrawal Period (days)
Chickens	For the control of chronic respiratory disease	5	820 mg/litre water (50-200 mg tylosin/kg bw)	1	Zero
Chickens	As an aid in the control of outbreaks of necrotic enteritis caused by <i>Clostridium perfringens</i>	5	250 mg/litre water (20-50 mg tylosin/kg bw)	Zero	Zero
Pigs	For the prevention and control of enzootic pneumonia and scours caused by organisms (e.g. <i>Lawsonia intracellularis</i>) sensitive to tylosin	3-10	412 mg/litre water (25 mg tylosin/kg bw)	Zero	N/A

STORAGE CONDITION

Store in a cool and dry room ($\leq 30^{\circ}\text{C}$). Keep away from direct sunlight

After first opening : Use within 7 days

After dilution : 24 hours

Date of Revision : 16th January 2019

Mal no. :
Packaging : 150g
Exp date :
Mfg date :

Manufactured By:

Nam Pharma Sdn. Bhd.

No. 5, Lebuhr Perusahan Klebang 11,
Taman Perindustrian Antarabangsa IBG,
31200 Chemor, Perak, Malaysia.

Product Registration Holder and Marketing By:

F.E Venture Sdn. Bhd.

Lot 3 & 5, Jalan PJS 11/8, Bandar Sunway,
46150 Petaling Jaya, Selangor D.E., Malaysia