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Elanco UK AH Limited

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Tylan Soluble Powder for oral solution

Species: Cattle, Chickens, Pigs, Turkeys

Therapeutic indication:Pharmaceuticals: Antimicrobials: Oral preparations: Others

Active ingredient: Tylosin Tartrate

Product: Tylan Soluble Powder for oral solution

Product index: Tylan Soluble Powder for oral solution

Cattle - meat:14 days

Pig - meat: Zero days

Poultry - meat:see notes

Poultry - eggs: Zero days

Withdrawal notes: Poultry meat - Chickens: Zero Days @ 20-50 mg/kg; 1 day @ 50-200mg/kg. Turkeys: Zero Days

Incorporating:

Qualitative and quantitative composition

Each 1.1g of the veterinary medicinal product contains

Active substance:

1000mg of tylosin (equivalent to 1100mg of tylosin tartrate)

Pharmaceutical form

Powder for oral solution

A white to medium yellow powder.

Clinical particulars

Target species

For use in calves, pigs, chickens and turkeys .

Indications for use, specifying the target species

For the control of *Mycoplasma synoviae* airsacculitis in chickens and *Mycoplasma gallisepticum* S6 in chickens and turkeys. 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*.

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

For the control of pneumonia in cattle associated with mycoplasmata and *Pasteurella multocida* sensitive to tylosin.

For information regarding swine dysentery see section Special precautions for use.

Contraindications

Do not use in cases of hypersensitivity to the active substance or other macrolides.

Special warnings for each target species

None

Special precautions for use

Special precautions for use in the target species

Use of the product be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

A high rate of in vitro resistance has been demonstrated in European strains of *Brachyspira hyodysenteriae* implying that the product will not be sufficiently efficacious against swine dysentery.

Use of the product deviating from the instructions given in the SPC 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 cross-resistance.

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

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 conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143. 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.

Adverse reactions (frequency and seriousness)

None known

Use during pregnancy, lactation or lay

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

Interaction with other medicinal products and other forms of interaction

None known

Amounts to be administered and administration route

For oral administration through drinking water.

In calves, the veterinary medicinal product corresponds to 1 gram of tylosin. The dosages are as follows:

C*hickens and turkeys:*
For the control of chronic respiratory disease: 50-200mg tylosin per kg BW per day (corresponding to 55-220mg of the veterinary medicinal product per kg BW) for 5 days.

As an aid in the control of outbreaks of necrotic enteritis caused by *Clostridium perfringens* in chickens: 20-50 mg/kg tylosin per/kg BW per day (corresponding to 22-55mg of the veterinary medicinal product per kg BW), depending on the age and the water consumption of the birds.

Pigs:

For the treatment of enzootic pneumonia: 25 mg tylosin/kg BW (corresponding to 27.5 mg of the veterinary medicinal product per kg BW). A medicated solution of drinking water should generally be administered until 24 hours after scouring or respiratory symptoms have ceased, normally 3-10 days. The diagnosis should be reviewed if there is no response after 5 days of medication.

For the treatment of ileitis:

5 – 10 mg tylosin per kg BW per day (corresponding to 5.5 – 11 mg of the veterinary medicinal product per kg BW) for 3 – 10 days.

Calves:

1.1 g of the veterinary medicinal product should be incorporated in milk or milk replacer twice daily for each calf. This should be continued for 7-14 days dependent on response.

The intake of medicated water/milk/milk replacer depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of tylosin may need to be adjusted accordingly.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

.....mg veterinary medicinal product per kg body weight per day	X	average body weight (kg) of animals to be treated	=. lit
	average daily water or milk intake (l/animal)		

Overdose (symptoms, emergency procedures, antidotes), if necessary

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

Withdrawal periods

Animals must not be slaughtered for human consumption during treatment.

Chickens, when the veterinary medicinal product is used for the control of chronic respiratory disease:

Meat and offal: 1 day

Eggs: Zero days

Chickens, when the veterinary medicinal product is used as an aid in the control of outbreaks of necrotic enteritis caused by *Clostridium perfringens* (Meat, offal and eggs): Zero days

Turkeys (meat and offal): Zero days

Pigs (meat and offal): Zero days

Calves (meat and offal): 14 days

Pharmacological particulars

Pharmacotherapeutic group: Macrolides, ATCvet code: QJ01FA90

Pharmacodynamic properties

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.

Pharmacokinetic particulars

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.

Pharmaceutical particulars

List of excipients

None

Incompatibilities

None known

Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after dilution according to directions: 24 hours

Shelf life after first opening the immediate packaging: use immediately.

Special precautions for storage

Store in the original container.

Keep the container tightly closed.

Do not store above 25°C. Store in a dry place.

Nature and composition of immediate packaging

110g high density polythene bottle with screw caps 1.1kg or block-bottomed laminated aluminium/polythene/paper bag.

Not all pack sizes may be marketed.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

Marketing Authorisation Holder (if different from distributor)

Elanco GmbH

Heinz-Lohmann Strasse 4

D-27472 Cuxhaven

Germany

Marketing Authorisation Number

Great Britain: Vm 52127/5122

Northern Ireland: 52127/3047

Significant changes

Date of the first authorisation or date of renewal

Date: 25 May 1993

Date of revision of the text

October 2025

Any other information

Legal category

Legal category:POM-V

GTIN

GTIN description: Tylan Soluble Powder for oral solution 100g Bottle

GTIN:05014602853105

NOAH Compendium

GTIN description: Tylan Soluble Powder for oral solution 1kg

GTIN:05014602853099