

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylan Soluble Powder for Oral Solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

### Active substance:

Tylosin 100g activity per bottle as Tylosin Tartrate.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Powder for oral solution. A white to medium yellow powder.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Tylan Soluble is indicated for use in calves, pigs and poultry.

### 4.2 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 4.5.

### 4.3 Contraindications

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

Do not use in animals with known hypersensitivity to tylosin or other macrolides.

#### **4.4 Special warnings for each target species**

None.

#### **4.5 Special precautions for use**

##### **Special precautions for use in animals**

Use of this 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. Whenever possible the product should only be used on the basis of susceptibility testing. 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 potential of cross-resistance.

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.

##### **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.

#### **4.6 Adverse reactions (frequency and seriousness)**

In very rare cases, the following adverse reactions have been observed in pigs administered tylosin at the recommended dose:

- Oedema of the rectal mucosa, partial anal protrusion (rosebudding), erythema and pruritis in pigs
- Red and irritated vagina
- Aggression

No specific adverse reactions relating to cattle, chickens or turkeys have been identified.

#### **4.7 Use during pregnancy, lactation or lay**

No adverse effects to tylosin have been seen in fertility, multigeneration or teratology studies.

#### **4.8 Interaction with other medicinal products and other forms of interactions**

None known.

#### **4.9 Amounts to be administered and administration route**

For oral administration.

*Recommendations for use in chickens and turkeys:*

For the control of chronic respiratory disease, Tylan Soluble is administered in the drinking water at a concentration of 0.5 g per litre for 5 days.

As an aid in the control of outbreaks of necrotic enteritis caused by *Clostridium perfringens* in chickens use Tylan in the drinking water for 5 days at a concentration of 0.15 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:*

Tylan Soluble is administered in the drinking water to provide 25 mg tylosin/kg bodyweight. This may normally be achieved by adding 0.25 g per litre. 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.

Tylan Soluble requirements per tonne of pigs daily:

Disease Treatment	Tylan Soluble required	Approx. water consumption
Enzootic pneumonia	25 g	100 litres
Ileitis	5 - 10 g	100 litres

*Recommendations for use in calves:*

The tylosin tartrate may be incorporated into the milk or reconstituted milk replacer at the time of feeding.

One gram of tylosin activity should be incorporated in milk or milk replacer twice daily for each calf to provide 40 mg tylosin per kg bodyweight. This should be continued for 7-14 days dependent on response.

The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of Tylan Soluble has to be adjusted accordingly. To ensure a correct dosage, body weight should be determined as accurately as possible to avoid under-dosing.

#### **4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary**

There is no evidence of tylosin toxicity in rats, at dose rates of up to 1000 mg/kg. There is no evidence of tylosin toxicity in Chickens, Turkeys, Pigs or Calves when administered Tylan soluble at up to three times the recommended dose.

#### **4.11 Withdrawal period(s)**

Pigs and Turkeys: Zero days

Chickens (meat): 150 mg/l dose: Zero days

Chickens (meat): 500 mg/l dose: 1 day

Chicken (eggs): Zero days

Calves: 14 days

### **5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group:

Antibacterials for systemic use; Macrolides, Lincosamides and Streptogramins,

ATCvet code: QJ01FA90

## 5.1 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.

## 5.2 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.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

None.

### 6.2 Major incompatibilities

None known.

### 6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 42 months

Shelf-life after dilution according to directions: 24 hours

Any medicated water which is not consumed within 24 hours should be discarded.

### 6.4 Special precautions for storage

Store in tightly closed original container.

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

## **6.5 Nature and composition of immediate packaging**

Tylan Soluble is presented in high density polythene bottles with screw caps containing 100g tylosin activity.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Elanco GmbH  
Heinz-Lohmann-Strasse 4  
27472 Cuxhaven  
Germany

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA22020/020/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 1<sup>st</sup> October 1988  
Date of last renewal: 23<sup>rd</sup> January 2009

## **10 DATE OF REVISION OF THE TEXT**

July 2018