SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylan Soluble Powder for Oral Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1.1 g of the veterinary medicinal product contains
Active substance:
1000 mg of tylosin (equivalent to 1100 mg of tylosin tartrate)

Excipients:

None

A white to medium yellow powder.

3. CLINICAL INFORMATION

3.1 Target species

For use in calves, pigs, chickens and turkeys.

3.2 Indications for use for each 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 3.5.

3.3 Contraindications

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the product should 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.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

Not applicable.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

For oral administration through drinking water.
In calves, the veterinary medicinal product can also be administered through milk or milk replacer.

1.1 gram of the veterinary medicinal product corresponds to 1 gram of tylosin.
The

dosages are as follows:

Chickens and turkeys:
For the control of chronic respiratory disease: 50 – 200 mg tylosin per kg BW per day (corresponding to 55 – 220 mg 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 tylosin per kg BW per day (corresponding to 22-55 mg of the veterinary medicinal product per kg BW) for 5 days, 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:

$$\frac{\text{…… mg veterinary medicinal product per kg body weight per day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily water or milk intake (l/animal)}} = \text{…...mg veterinary medicinal product per litre of drinking water or milk}$$

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01FA90

4.2 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.

4.3 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after dissolution according to directions: 24 hours
Shelf life after first opening the immediate packaging: use immediately.

5.3 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.

5.4 Nature and composition of immediate packaging

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

Not all pack sizes may be marketed.

5.5 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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd

7. MARKETING AUTHORISATION NUMBER

Vm 00879/4175

8. DATE OF FIRST AUTHORISATION

25 May 1993

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

June 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 18 July 2025