1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylan Soluble Powder for Oral Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:
Active substance:
Tylosin (Tylosin Tartrate) 1000 mg

Excipients:
None

A white to medium yellow powder.

3. CLINICAL INFORMATION

3.1 Target species

Calves, pigs, chickens and turkeys.

3.2 Indications for use for each target species

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

For the treatment and metaphylaxis of necrotic enteritis in chickens caused by *Clostridium perfringens.*

For the treatment and metaphylaxis of enzootic pneumonia, and scours caused by organisms (e.g. *Lawsonia intracellularis*) sensitive to tylosin, in pigs. For information regarding swine dysentery see section 3.5.

For the treatment and metaphylaxis of pneumonia in cattle associated with mycoplasmata and *Pasteurella multocida* sensitive to tylosin.
The presence of the disease in the group or flock must be established before the product is used.

3.3 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 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. 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 package leaflet or label to the physician. 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.

3.6 Adverse events

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Aggression Rectal prolapse[1], Rectal oedema Erythema, Pruritus, Skin irritation[2] Red mucosae[2]

[1] Partial anal protrusion (rosebudding)
[2] Vaginal.

Calves, chickens and turkeys: 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

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

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Pigs, chickens, turkeys: In drinking water use.
Calves: In drinking milk/milk replacer use.

Recommendations for use in chickens and turkeys:
For the treatment and metaphylaxis of chronic respiratory disease the veterinary medicinal product is administered in the drinking water at a concentration of 0.5 g per litre for 5 days.

For the treatment and metaphylaxis of necrotic enteritis caused by *Clostridium perfringens* in chickens use the veterinary medicinal product 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:
The veterinary medicinal product 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.

Veterinary medicinal product requirements per tonne of pigs daily:

Disease Treatment	Veterinary medicinal product 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/milk/ milk replacer depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of the veterinary medicinal product may need to be adjusted accordingly.
To ensure a correct dosage, body weight should be determined as accurately as possible.

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

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 the veterinary medicinal product at up to three times the recommended dose.

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

Pigs and Turkeys (meat and offal): Zero days.
Chickens (meat and offal): 150 mg/l dose: Zero days.
Chickens (meat and offal): 500 mg/l dose: 1 day.
Chicken (eggs): 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: 42 months
Shelf-life after dilution according to directions: 24 hours
Any medicated water which is not consumed within 24 hours should be discarded.

5.3 Special precautions for storage

Store in tightly closed original container.
Do not store above 25 °C. Store in a dry place.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is presented in 100 g high density polythene bottles with screw caps containing 100g tylosin activity.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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 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 GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA22020/020/001

8. DATE OF FIRST AUTHORISATION

01 October 1988

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

23 April 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).