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.
Tylosin 1000g activity per bag 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

For use in calves, pigs, chickens and turkeys .

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 to wildlife.

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

4.4 Special warnings for each target species

None

4.5 Special precautions for use

i) Special 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.

Official, national and regional antimicrobial policies should be taken into account when the product is used.
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.

ii) 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)

None known

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

For oral administration.

Recommendations for use in chickens and turkeys:
Tylan Soluble is administered in the drinking water at a concentration of 0.5 g per litre.

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 0.25g per litre.

Recommendations for use in calves:
One gram of tylosin activity per calf administered orally twice daily for seven to fourteen days. The tylosin tartrate may be incorporated into the milk or reconstituted milk replacer at the time of feeding.

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid under-dosing.Recommended programmes
a) Chickens and turkeys
For preventative medication the following programmes are recommended:

As an aid to mycoplasmosis prevention in chickens:

Class of Stock	Age	Tylan Soluble at 0.5g per litre
Broiler	0-3 days	35 g per 1000 birds
	4th week of life	35 g per 1000 birds
Layers and replacement pullets	0-3 days	35 g per 1000 birds
	4th week of life	35 g per 1000 birds
	9-12th week	48 hours medication
	16th-20th week	48 hours medication
Breeders	0-3 days	50 g per 1000 birds
	4th week of life	80 g per 1000 birds
	9th, 12th, 16th, 20th, 24th weeks of age	48 hours medication

As an aid to mycoplasmosis prevention in turkeys:

Class of Stock	Age	Tylan Soluble at 0.5g per litre
Table Turkeys	0-5 days	12.5 g per 100 birds
	4th week of life	7.5 g per 100 birds

For treatment of mycoplasmosis:

Class of Stock	Tylan Soluble at 0.5g per litre
Broilers	24-72 hours medication
Layers and replacement pullets	48-72 hours medication
Turkeys	48-120 hours medication

As an aid in the control of necrotic enteritis:

Class of Stock	Tylan Soluble at 0.15g per litre
Broilers	5 days
Layers and Replacement pullets	5 days

b) Pigs

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	Water consumption (l) approx.
enzootic pneumonia	25 g	100 litres
Ileitis	5-10 g	100 litres

c) Calves

One gram of tylosin activity 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 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.

4.10 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.

4.11 Withdrawal periods

Species	Indications	Treatment Duration (days)	Dose	Meat Withdrawal Period (days)	Egg Withdrawal period (days)
Chickens	For the control of chronic respiratory disease	5	500 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 *Clostridium perfringens*.	5	150 mg /litre water (20-50 mg tylosin/kg bw)	**Zero**	**Zero**
Turkeys	For the control of chronic respiratory disease	5	500 mg/litre water	**Zero**	**N/A**
Pigs	For the prevention and control of enzootic pneumonia, swine dysentery and other scours caused by organisms (e.g. *Lawsonia intracellularis*) sensitive to tylosin	3-10	250 mg/litre water (25 mg tylosin/kg bw)	**Zero**	**N/A**
Calves	For the control of pneumonia associated with mycoplasmata and *Pasteurella multocida* sensitive to tylosin.	7-14	1000 mg per calf twice daily	**14**	**N/A**

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Macrolides,
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 Incompatibilities

None known

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after dilution according to directions: 24 hours

6.4 Special precautions for storage

Store in tightly closed original container.
Do not store above 25°C. Store in a dry place.
Any medicated water which is not consumed within 24 hours should be discarded.

6.5 Nature and composition of immediate packaging

Tylan Soluble is presented in high density polythene bottles with screw caps containing 100g tylosin activity, or block-bottomed laminated aluminium/polythene/paper bags containing 1000g tylosin activity.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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 Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

8. MARKETING AUTHORISATION NUMBER

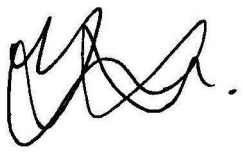
Vm 00879/4175

9. DATE OF FIRST AUTHORISATION

25 May 1993

10. DATE OF REVISION OF THE TEXT

September 2020



Approved: 24 September 2020