# PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
# 110 g BOTTLE

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylan Soluble Powder for oral solution

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each 1.1 g of the veterinary medicinal product contains
**Active substance:**
1000 mg of tylosin (equivalent to 1100 mg of tylosin tartrate)
A white to medium yellow powder.

## 3. TARGET SPECIES

For use in calves, chickens, turkeys, and pigs.

## 4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

## 5. WITHDRAWAL PERIODS

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

## 6. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life after dissolution according to directions: 24 hours.
Shelf life after first opening the bottle: use immediately.

## 7. SPECIAL STORAGE PRECAUTIONS

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

## 8. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

## 9. BATCH NUMBER

Lot {number}

# PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

## 110 g BOTTLE

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Tylan Soluble Powder for oral solution

### 2. Composition

Each 1.1 g of the veterinary medicinal product contains
**Active substance:**
1000 mg of tylosin (equivalent to 1100 mg of tylosin tartrate)
A white to medium yellow powder.

### 3. Target species

For use in calves, chickens, turkeys, and pigs.

### 4. Indications for use

For the control of bovine pneumonia associated with bovine respiratory *Mycoplasma* or *Pasteurella multocida* sensitive to tylosin.

As an aid in the control of outbreaks of necrotic enteritis in chickens caused by *Clostridium perfringens.*

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 as-sociated with live vaccination.

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

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.

### 5. Contraindications

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

### 6. Special warnings

Special precautions for safe use in the target species:

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 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.
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 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.

Fertility:
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.

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

Major incompatibilities:

None known.

## 7. Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

## 8. Dosage for each species, routes and method of administration

**Treatment**:
Medicates 7 calves for one week.
Medicates 200 litres of water for the treatment of chickens and turkeys (respiratory disease).
Medicates 400 - 2000 litres of water for the treatment of pigs.
Medicates 666 litres of water for the treatment of chickens (necrotic enteritis).

**Dosage and Administration**
1.1 gram of the veterinary medicinal product corresponds to 1 gram of tylosin. The dosages are as follows:

**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.

**Chickens and turkeys: 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.

**Chickens: Necrotic Enteritis**
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: 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.

**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.

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 to avoid under-dosing.

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:

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

## 9. Advice on correct administration

## 10. Withdrawal periods

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

## 11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after dissolution according to directions: 24 hours
Shelf life after first opening the immediate packaging: use immediately.

## 12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## 13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

## 14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 52127/5122
Vm 52127/3047

**Pack sizes**
110 g bottle
1.1 kg bag
Not all pack sizes may be marketed.

## 15. PID link (Do not print heading)

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

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

## 16. Contact details

Marketing authorisation holder:

Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
27472 Cuxhaven
Germany

Contact details to report suspected adverse reactions:

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

Tel: +44 3308221732

PV.GBR@elancoah.com

Manufacturer responsible for batch release:

Elanco France S.A.S.
26 rue de la Chapelle,
68330 Huningue,
France

## 17. Other information

POM-V

Veterinary medicinal product subject to prescription

For animal treatment only.

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet 1.1 kg BAG**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylan Soluble Powder for oral solution

## 2. COMPOSITION

Each 1.1 g of the veterinary medicinal product contains
**Active substance:**
1000 mg of tylosin (equivalent to 1100 mg of tylosin tartrate)
A white to medium yellow powder.

## 3. PACKAGE SIZE

1.1 kg

## 4. TARGET SPECIES

For use in calves, chickens, turkeys, and pigs.

## 5. INDICATIONS FOR USE

### Indications for use

For the control of bovine pneumonia associated with bovine respiratory *Mycoplasma* or *Pasteurella multocida* sensitive to tylosin.

As an aid in the control of outbreaks of necrotic enteritis in chickens caused by *Clostridium perfringens*.

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 as-sociated with live vaccination.

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

## 6. CONTRAINDICATIONS

### Contraindications

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

## 7. SPECIAL WARNINGS

### Special warnings

Special precautions for safe use in the target species:

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 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.

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 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.

Fertility:

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

Interactions with other medicinal products and other forms of interaction:

None known.

Overdose:

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

Major incompatibilities:

None known.

## 8. ADVERSE EVENTS

### Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details on this label, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

## 9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

### Dosage for each species, routes and method of administration

**Treatment**
Medicates 70 calves for one week.
Medicates 2000 litres of water for the treatment of chickens and turkeys (respiratory disease).
Medicates 4000 litres of water for the treatment of pigs.
Medicates 6666 litres of water for the treatment of chickens (necrotic enteritis).

**Dosage and Administration**
1.1 gram of the veterinary medicinal product corresponds to 1 gram of tylosin. The dosages are as follows:

**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.

**Chickens and turkeys:**
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.

**Chickens:**
Necrotic Enteritis**:**
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:**
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.

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.

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 to avoid under-dosing.
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:

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

## 10. ADVICE ON CORRECT ADMINISTRATION

### Advice on correct administration

## 11. WITHDRAWAL PERIODS

### 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

## 12. SPECIAL STORAGE PRECAUTIONS

### Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

## 13. SPECIAL PRECAUTIONS FOR DISPOSAL

### Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## 14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

### Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

## 15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 52127/5122
Vm 52127/3047

**Pack sizes**
110 g bottle
1.1 kg bag
Not all pack sizes may be marketed.

## 16. PID LINK (Do not print heading)

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

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

## 17. CONTACT DETAILS

**Contact details**

Marketing authorisation holder:

Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
27472 Cuxhaven
Germany

Contact details to report suspected adverse reactions:

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom
Tel: +44 3308221732
PV.GBR@elancoah.com

Manufacturer responsible for batch release:

Elanco France S.A.S
26 rue de la Chapelle,
68330 Huningue
France

## 18. OTHER INFORMATION

### Other information

POM-V

Veterinary medicinal product subject to prescription

## 19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

## 20. EXPIRY DATE

Exp {mm/yyyy}

Shelf life after dissolution according to directions: 24 hours.

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

## 21. BATCH NUMBER

Lot {number}

*Gavin Hall*
Approved: 01 September 2025