PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Front + back labels for 1 kg bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylan Soluble Powder for oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Ingredients
This pack contains tylosin tartrate equivalent to 1000 g tylosin base activity.

3. PHARMACEUTICAL FORM

Powder for oral solution

4. PACKAGE SIZE

1 Kg

5. TARGET SPECIES

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

6. INDICATION(S)

For the prevention and treatment 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 broiler chickens and *Mycoplasma gallisepticum* S6 in chickens and turkeys.
For the prevention and control of enzootic pneumonia and scours caused by organisms (e.g. *Lawsonia intracellularis*) sensitive to tylosin in pigs.

7. METHOD AND ROUTE(S) 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
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.

Calves: One gram of Tylan Soluble per calf administered orally twice daily for seven to fourteen days.
The product may be incorporated into the milk or reconstituted milk replacer at the time of feeding.

Chickens and turkeys: Respiratory Disease
Tylan Soluble is administered in the drinking water at a concentration of 0.5 g per litre.

Recommended programmes for chickens and turkeys are as follows:

Class of Stock	Age	Tylan Soluble at 0.5 g per litre
Broilers	0-3 days 4th week of life	35 g per 1000 birds

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

For treatment of mycoplasmosis

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

Chickens: Necrotic Enteritis
Tylan Soluble is administered in the drinking water at a concentration of 0.15 g per litre.

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

Pigs:
Ileitis:
A medicated solution of drinking water should be administered until 24 hours after scouring or coughing has ceased. The diagnosis should be reviewed if no response after 5 days of medication.

Treatment of:	Tylan Soluble required	Water consumption (appox.)
Enzootic pneumonia	25 g	100 litres
Illeitis	5-10 g	100 litres

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Animals must not be slaughtered for human consumption during treatment.

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 and 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**

9. SPECIAL WARNING(S), IF NECESSARY

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 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. 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 crossresistance.

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

Operator warnings:
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.

10. EXPIRY DATE

Use Before: {month/year}

11. SPECIAL STORAGE CONDITIONS

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.
Once opened the entire contents of the bag must be added to the requisite quantity of water.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with national requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

FOR ANIMAL TREATMENT ONLY. TO BE SUPPLIED ONLY ON VETERINARY PRESCRIPTION.

POM-V

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 00879/4175

17. MANUFACTURER'S BATCH NUMBER

Lot No.:{number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Booklet label for 100g bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylan Soluble Powder for oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

100 g tylosin activity
Tylosin tartrate

3. PHARMACEUTICAL FORM

Powder for oral solution
Tylan Soluble is presented as a soluble powder for water medication.

4. PACKAGE SIZE

100 g

5. TARGET SPECIES

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

6. INDICATION(S)

For the prevention and treatment 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 broiler chickens and *Mycoplasma gallisepticum* S6 in chickens and turkeys.
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.

7. METHOD AND ROUTE(S) 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).
Mixing Directions: See attached leaflet.
Dosage: See attached leaflet

Dosage and Administration
Calves: One gram of Tylan Soluble per young calf administered orally twice daily for seven to fourteen days. The product may be incorporated into the milk or reconstituted milk replacer at the time of feeding.
Chickens and turkeys: Respiratory Disease
Tylan Soluble is administered in the drinking water at a concentration of 0.5 g per litre.

Recommended programmes for chickens and turkeys are as follows:

Class of Stock	Age	Tylan Soluble at 0.5 g per litre
Broilers	0-3 days 4th week of life	35 g per 1000 birds

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

For treatment of mycoplasmosis

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

Chickens: Necrotic Enteritis
Tylan Soluble is administered in the drinking water at a concentration of 0.15 g per litre.

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

Pigs:
Ileitis:
A medicated solution of drinking water should be administered until 24 hours after scouring or coughing has ceased. The diagnosis should be reviewed if no response after 5 days of medication.

Tylan Soluble requirements per tonne of pigs daily:

Treatment of:	Tylan Soluble required	Water consumption (appox.)
Enzootic pneumonia	25 g	100 litres
Illeitis	5-10 g	100 litres

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 been adjusted accordingly.
To ensure a correct dosage, body weight should be determined as accurately as possible to avoid under-dosing.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Animals must not be slaughtered for human consumption during treatment.
Calves: 14 days
Chicken (meat): (150 mg/l dose): Zero days
(500 mg/l dose): 1 day
Chicken (eggs): Zero days
Turkeys and pigs: Zero days

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 and 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**

9. SPECIAL WARNING(S), IF NECESSARY

Contra-indications:
Do not use in known cases of hypersensitivity to tylosin or other macrolides.

Operator Warnings: To avoid exposure during preparation of the medicated drinking water, wear overalls, safety glasses, impervious gloves, and a mask. 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. Macrolides may occasionally cause severe allergic reactions. See package leaflet for full user warnings.

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.
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 crossresistance.

Operator warnings: 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.

10. EXPIRY DATE

Use Before: {month/year}

11. SPECIAL STORAGE CONDITIONS

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.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with national requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. TO BE SUPPLIED ONLY ON VETERINARY PRESCRIPTION.

UK Only
Prescription Only Medicine – Veterinary

POM-V

IE Only
Prescription Only Medicine

POM

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBERS

UK: Vm 00879/4175
IE: VPA 22020/020/001

17. MANUFACTURER'S BATCH NUMBER

Lot No {number}

OTHER INFORMATION

Site of Batch Release:

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

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Front + back labels for 1 kg bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylan Soluble Powder for oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Ingredients
This pack contains tylosin tartrate equivalent to 1000 g tylosin base activity.

3. PHARMACEUTICAL FORM

Powder for oral solution

4. PACKAGE SIZE

1 Kg

5. TARGET SPECIES

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

6. INDICATION(S)

For the prevention and treatment 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 broiler chickens and *Mycoplasma gallisepticum* S6 in chickens and turkeys.
For the prevention and control of enzootic pneumonia and scours caused by organisms (e.g. *Lawsonia intracellularis*) sensitive to tylosin in pigs.

7. METHOD AND ROUTE(S) 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
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.

Calves: One gram of Tylan Soluble per calf administered orally twice daily for seven to fourteen days.
The product may be incorporated into the milk or reconstituted milk replacer at the time of feeding.

Chickens and turkeys: Respiratory Disease
Tylan Soluble is administered in the drinking water at a concentration of 0.5 g per litre.

Recommended programmes for chickens and turkeys are as follows:

Class of Stock	Age	Tylan Soluble at 0.5 g per litre
Broilers	0-3 days 4th week of life	35 g per 1000 birds

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

For treatment of mycoplasmosis

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

Chickens: Necrotic Enteritis
Tylan Soluble is administered in the drinking water at a concentration of 0.15 g per litre.

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

Pigs:
Ileitis:
A medicated solution of drinking water should be administered until 24 hours after scouring or coughing has ceased. The diagnosis should be reviewed if no response after 5 days of medication.

Treatment of:	Tylan Soluble required	Water consumption (appox.)
Enzootic pneumonia	25 g	100 litres
Illeitis	5-10 g	100 litres

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Animals must not be slaughtered for human consumption during treatment.

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 and 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**

9. SPECIAL WARNING(S), IF NECESSARY

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 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. 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 crossresistance.

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

Operator warnings:
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.

10. EXPIRY DATE

Use Before: {month/year}

11. SPECIAL STORAGE CONDITIONS

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.
Once opened the entire contents of the bag must be added to the requisite quantity of water.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with national requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

FOR ANIMAL TREATMENT ONLY. TO BE SUPPLIED ONLY ON VETERINARY PRESCRIPTION.

POM-V

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 00879/4175

17. MANUFACTURER'S BATCH NUMBER

Lot No.:{number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Booklet label for 100g bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylan Soluble Powder for oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

100 g tylosin activity
Tylosin tartrate

3. PHARMACEUTICAL FORM

Powder for oral solution
Tylan Soluble is presented as a soluble powder for water medication.

4. PACKAGE SIZE

100 g

5. TARGET SPECIES

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

6. INDICATION(S)

For the prevention and treatment 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 broiler chickens and *Mycoplasma gallisepticum* S6 in chickens and turkeys.
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.

7. METHOD AND ROUTE(S) 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).
Mixing Directions: See attached leaflet.
Dosage: See attached leaflet

Dosage and Administration
Calves: One gram of Tylan Soluble per young calf administered orally twice daily for seven to fourteen days. The product may be incorporated into the milk or reconstituted milk replacer at the time of feeding.
Chickens and turkeys: Respiratory Disease
Tylan Soluble is administered in the drinking water at a concentration of 0.5 g per litre.

Recommended programmes for chickens and turkeys are as follows:

Class of Stock	Age	Tylan Soluble at 0.5 g per litre
Broilers	0-3 days 4th week of life	35 g per 1000 birds

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

For treatment of mycoplasmosis

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

Chickens: Necrotic Enteritis
Tylan Soluble is administered in the drinking water at a concentration of 0.15 g per litre.

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

Pigs:
Ileitis:
A medicated solution of drinking water should be administered until 24 hours after scouring or coughing has ceased. The diagnosis should be reviewed if no response after 5 days of medication.

Tylan Soluble requirements per tonne of pigs daily:

Treatment of:	Tylan Soluble required	Water consumption (appox.)
Enzootic pneumonia	25 g	100 litres
Illeitis	5-10 g	100 litres

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 been adjusted accordingly.
To ensure a correct dosage, body weight should be determined as accurately as possible to avoid under-dosing.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Animals must not be slaughtered for human consumption during treatment.
Calves: 14 days
Chicken (meat): (150 mg/l dose): Zero days
(500 mg/l dose): 1 day
Chicken (eggs): Zero days
Turkeys and pigs: Zero days

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 and 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**

9. SPECIAL WARNING(S), IF NECESSARY

Contra-indications:
Do not use in known cases of hypersensitivity to tylosin or other macrolides.

Operator Warnings: To avoid exposure during preparation of the medicated drinking water, wear overalls, safety glasses, impervious gloves, and a mask. 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. Macrolides may occasionally cause severe allergic reactions. See package leaflet for full user warnings.

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.
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 crossresistance.

Operator warnings: 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.

10. EXPIRY DATE

Use Before: {month/year}

11. SPECIAL STORAGE CONDITIONS

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.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with national requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. TO BE SUPPLIED ONLY ON VETERINARY PRESCRIPTION.

UK Only
Prescription Only Medicine – Veterinary

POM-V

IE Only
Prescription Only Medicine

POM

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBERS

UK: Vm 00879/4175
IE: VPA 22020/020/001

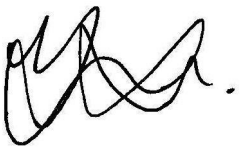
17. MANUFACTURER'S BATCH NUMBER

Lot No {number}

OTHER INFORMATION

Site of Batch Release:

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



Approved: 24 May 2023