

PROPOSED PRODUCT LABEL PROFILE
TYLAN 100 PREMIX

ELANCO™

AF0099

Pr-Tylan™ 100
tylosin phosphate premix

FOR VETERINARY USE ONLY
ANTIBIOTIC

Net Weight 25 kg
DIN 02242023

FOR USE IN SWINE, BEEF CATTLE AND BROILER CHICKEN FEEDS ONLY

ACTIVE INGREDIENT

tylosin (as tylosin phosphate).....220 grams per kilogram of premix

INDICATIONS

A. Swine:

- I. For use as an aid in the treatment and the prevention of cyclic recurrence of swine dysentery (bloody scours, bloody diarrhea, black scours, hemorrhagic colitis, vibrio).
- II. For use as an aid in the prevention of porcine proliferative enteropathy (PPE) or ileitis associated with *Lawsonia intracellularis*.
- III. As an aid in the treatment of porcine proliferative enteropathy (PPE) or ileitis associated with *Lawsonia intracellularis* when used following treatment with Tylan Soluble.
- IV. For the treatment of porcine proliferative enteropathy (PPE) or ileitis associated with *Lawsonia intracellularis*.
- V. For the treatment of porcine proliferative enteropathy (PPE) or ileitis associated with *Lawsonia intracellularis* in the presence of persistent or recurring infection.
- VI. For use as an aid in the prevention of subclinical porcine proliferative enteropathy (PPE) or ileitis associated with *Lawsonia intracellularis*.

B. Beef Cattle: To reduce the incidence of liver abscesses caused by *Trueperella pyogenes* and *Fusobacterium necrophorum* in beef cattle (steers and heifers) fed in confinement for slaughter.

C. Broiler Chickens: As an aid in the treatment of necrotic enteritis caused by *Clostridium perfringens* in broiler chickens.

DOSAGE AND ADMINISTRATION

To reduce the development of antimicrobial resistance and maintain effectiveness, use this antibiotic prudently and for the shortest duration required to achieve the desired clinical outcome.

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TYLAN 100 PREMIX

IMPORTANT: Must be thoroughly mixed in feeds before use.

MIXING DIRECTIONS FOR SWINE

SWINE DYSENTERY

Indication I (a): Treatment in combination with Tylan Soluble

Concurrent with Tylan Soluble treatment of the disease administer Tylan 100 at the rate of 500 g (110 g tylosin) per 1,000 kg of complete feed for three weeks. The medicated drinking water, containing one gram of tylosin tartrate per U.S. gallon (3.785 litres) should be provided for the first three days of treatment, or until symptoms disappear.

Indication I (b): Prevention of recurrence following treatment

To prevent recurrence of swine dysentery, the level of premix should be reduced to 200 g (44 g tylosin) per 1,000 kg of complete feed until market weight. Feed as the sole ration.

PORCINE PROLIFERATIVE ENTEROPATHY (ILEITIS)

Indication II: Prevention

Administer Tylan 100 at a rate of 500 g (110 g tylosin) per 1,000 kg of complete feed. Feed as the sole ration for 21 days, commencing prior to an anticipated outbreak of disease.

Indication III: Treatment following administration of Tylan Soluble

As an aid in the treatment of porcine proliferative enteropathy (PPE) or ileitis associated with *Lawsonia intracellularis*, treat by way of drinking water with Tylan Soluble for 7 days at 1 gram per 12 litres (83 mg per litre) followed by Tylan 100 in the feed at a rate of 500 g (110 g tylosin) per 1,000 kg of complete feed for 7 days.

Indication IV: Treatment

To treat porcine proliferative enteropathy (PPE) or ileitis associated with *Lawsonia intracellularis*, administer Tylan 100 at a rate of 500 g (110 g tylosin) per 1,000 kg of complete feed for 3 weeks.

Indication V: Treatment in the presence of persistent or recurring infection

To treat porcine proliferative enteropathy (PPE) or ileitis associated with *Lawsonia intracellularis* in the presence of persistent or recurring infection, administer Tylan 100 at a rate of 0.5 kg (110 g tylosin) per 1,000 kg of complete feed for 3 weeks. Follow with Tylan 100 at a rate of 200 g (44 g tylosin) per 1,000 kg of complete feed for 3 weeks.

Indication VI: Prevention of subclinical form

Administer Tylan 100 at a rate of 200 g (44 g tylosin) per 1,000 kg of complete feed. Feed as the sole ration for 21 days, commencing prior to an anticipated subclinical manifestation of the disease. The best time to initiate medication should be determined by a veterinarian based on the use of appropriate diagnostic tools.

MIXING DIRECTIONS FOR BEEF CATTLE

Administer Tylan 100 at the rate of 50 g (11 g tylosin) per 1,000 kg of complete diet including roughage (100% dry matter basis). Feed continuously as the sole ration. Tylan premix can be used in

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TYLAN 100 PREMIX

the following thixotrope liquid supplement: Promolas Liquid Supplement Suspension, Westway Feed Products.

MIXING DIRECTIONS FOR BROILER CHICKENS

Administer Tylan 100 at a rate of 0.91 kg (200 g tylosin) per 1,000 kg of complete feed for the treatment of necrotic enteritis in broiler chickens. Feed as the sole ration for 7 days.

CAUTIONS

1. Do not use in replacement, breeding, or lactating cattle.
2. Not to be used in feeds containing pellet binding agents with the exception of Lignosol (4%) and Agri-Colloid (0.3%). Do not use in any supplement, concentrate or complete feed containing bentonite. May be used in a thixotrope liquid supplement with Rumensin™.
3. Do not use the thixotropic supplement after 8 weeks storage.
4. When treating swine dysentery or necrotic enteritis, the diagnosis should be redetermined in cases of lack of response within 3 to 5 days of treatment commencement.
5. When treating porcine proliferative enteropathy (PPE) or ileitis, the diagnosis should be confirmed when results are not satisfactory.

WARNINGS

1. Swine treated concurrently with this drug in complete feed and with tylosin tartrate in drinking water must not be slaughtered for use in food for at least 48 hours after the latest treatment with tylosin in drinking water.
2. No preslaughter withdrawal period is required when swine are treated with this drug at a level of 44 grammes or 110 grams of tylosin per 1,000 kg of complete feed *except when used concurrently with tylosin in drinking water.*
3. No preslaughter withdrawal periods are required for beef cattle and broiler chickens when treated according to the label.
4. Do not use in laying hens.
5. Do not use in lactating dairy cattle.
6. Keep out of reach of children.

STORAGE

Store in a cool dry place.

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PROPOSED PRODUCT LABEL PROFILE
TYLAN 100 PREMIX

ELANCO
Division Eli Lilly Canada Inc.
150 Research Lane, Suite 120,
Guelph, Ontario
N1G 4T2

<TAKE TIME
OBSERVE LABEL DIRECTIONS>
<Antimicrobial Prudent Use Logo>

Lot and Expiry are printed at the time of filling.

PROPOSED PRODUCT LABEL PROFILE
TYLAN 100 PREMIX TOTE

LOT

EXP

Tote #

ELANCO™

AF0099

PrTylan™ 100
tylosin phosphate premix

Net Weight 500 kg
DIN 02242023

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ANTIBIOTIC

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ACTIVE INGREDIENT

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B. Beef Cattle: To reduce the incidence of liver abscesses caused by *Trueperella pyogenes* and *Fusobacterium necrophorum* in beef cattle (steers and heifers) fed in confinement for slaughter.

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TYLAN 100 PREMIX TOTE

- C. Broiler Chickens: As an aid in the treatment of necrotic enteritis caused by *Clostridium perfringens* in broiler chickens.

DOSAGE AND ADMINISTRATION

To reduce the development of antimicrobial resistance and maintain effectiveness, use this antibiotic prudently and for the shortest duration required to achieve the desired clinical outcome.

IMPORTANT: Must be thoroughly mixed in feeds before use.

MIXING DIRECTIONS FOR SWINE

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Indication I (b): Prevention of recurrence following treatment

To prevent recurrence of swine dysentery, the level of premix should be reduced to 200 g (44 g tylosin) per 1,000 kg of complete feed until market weight. Feed as the sole ration.

PORCINE PROLIFERATIVE ENTEROPATHY (ILEITIS)

Indication II: Prevention

Administer Tylan 100 at a rate of 500 g (110 g tylosin) per 1,000 kg of complete feed. Feed as the sole ration for 21 days, commencing prior to an anticipated outbreak of disease.

Indication III: Treatment following administration of Tylan Soluble

As an aid in the treatment of porcine proliferative enteropathy (PPE) or ileitis associated with *Lawsonia intracellularis*, treat by way of drinking water with Tylan Soluble for 7 days at 1 gram per 12 litres (83 mg per litre) followed by Tylan 100 in the feed at a rate of 500 g (110 g tylosin) per 1,000 kg of complete feed for 7 days.

Indication IV: Treatment

To treat porcine proliferative enteropathy (PPE) or ileitis associated with *Lawsonia intracellularis*, administer Tylan 100 at a rate of 500 g (110 g tylosin) per 1,000 kg of complete feed for 3 weeks.

Indication V: Treatment in the presence of persistent or recurring infection

To treat porcine proliferative enteropathy (PPE) or ileitis associated with *Lawsonia intracellularis* in the presence of persistent or recurring infection, administer Tylan 100 at a rate of 500 g (110 g tylosin) per 1,000 kg of complete feed for 3 weeks. Follow with Tylan 100 at a rate of 200 g (44 g tylosin) per 1,000 kg of complete feed for 3 weeks.

Indication VI: Prevention of subclinical form

Administer Tylan 100 at a rate of 200 g (44 g tylosin) per 1,000 kg of complete

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feed. Feed as the sole ration for 21 days, commencing prior to an anticipated subclinical manifestation of the disease.

MIXING DIRECTIONS FOR BEEF CATTLE

Administer Tylan 100 at the rate of 50 g (11 g tylosin) per 1,000 kg of complete diet including roughage (100% dry matter basis). Feed continuously as the sole ration. Tylan can be used in the following thixotrope liquid supplement: Promolas Liquid Supplement Suspension, Westway Feed Products.

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CAUTIONS

1. Do not use in replacement, breeding, or lactating cattle.
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<Antimicrobial Prudent Use Logo>

