#### TYLAN 40- tylosin phosphate granule Elanco US Inc.

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AF0040

Elanco™

Tylan™40

ТМ

Net Weight: 50 lbs (22.68 kg)

Tylosin Phosphate

**Type A Medicated Article** 

**CAUTION:** Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.

#### For use in Swine and Beef Cattle Feeds Only

#### Do Not Feed Undiluted

Equivalent to **40 g** Tylosin per Pound

#### Swine:

For reduction in severity of effects of atrophic rhinitis.

For control of swine dysentery associated with Brachyspira hyodysenteriae.

For the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae* immediately after medicating with **Tylan Soluble** (tylosin) drinking water.

For control of porcine proliferative enteropathies (PPE, ileitis) associated with Lawsonia intracellularis.

For control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis* immediately after medicating with **Tylan Soluble** (tylosin) in drinking water.

#### **Beef Cattle:**

For reduction of incidence of liver abscesses associated with *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*.

#### Restricted Drug (California), Use only as Directed.

#### Approved by FDA under NADA # 012-491

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Manufactured For:

#### Elanco US Inc.

#### Greenfield, IN 46140, USA

To report adverse effects, access medical information, or obtain additional product information, call 1-800-428-4441.

BG102344X

AF0040

#### Elanco<sup>TM</sup>

Directions for Use Read All Directions Carefully Before Mixing and Feeding Tylan<sup>™</sup> 40 Type A Medicated Article Do Not Feed Undiluted. Net Weight: 50 lbs (22.68 kg)

# Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.

Active Drug Ingredient—Tylosin (as tylosin phosphate)...40 g per Ib

**Ingredients:** Roughage products, calcium carbonate and mineral oil.

**Caution:** To ensure adequate mixing, an intermediate blending step should be used prior to manufacturing a complete feed. Do not use in any liquid feed containing sodium metabisulfite or in any finished feed (supplement, concentrate or complete feed) containing in excess of 2% bentonite.

**Warning: Tylan 40** may be irritating to unprotected skin and eyes. When mixing and handling **Tylan 40** use protective clothing, impervious gloves and a dust respirator. In case of accidental eye exposure, flush eyes with plenty of water. Exposed skin should be washed with plenty of soap and water. Remove and wash contaminated clothing. Seek medical attention if irritation becomes severe or persists. The material safety data sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, access medical information, or obtain additional product information, call 1-800-428-4441.

**For reduction in severity of effects of atrophic rhinitis.** Feed 100 g of tylosin per ton (2.5 pounds **Tylan 40** per ton) of complete feed. Feed continuously as the sole ration.

**For control of swine dysentery.** Feed 100 g of tylosin per ton (2.5 pounds **Tylan 40** per ton) of complete feed for at least three weeks. Follow with 40 g tylosin per ton (1 pound **Tylan 40** per ton) of complete feed until pigs reach market weight.

**For the treatment and control of swine dysentery.** Feed 40 to 100 grams of tylosin (1.0 to 2.5 pounds of **Tylan 40**) per ton of complete feed for 2 to 6 weeks immediately after medicating with 250 mg tylosin (as **Tylan Soluble**) per gallon in drinking water for 3 to 10 days.

**For control of porcine proliferative enteropathies (PPE, ileitis).** Feed 100 g of tylosin per ton (2.5 pounds **Tylan 40** per ton) of complete feed for 21 days. Alternatively, feed 100 g of tylosin per ton (2.5 pounds **Tylan 40** per ton) of complete feed for at least three weeks, followed by 40 g tylosin per ton of complete feed until pigs reach market weight. Alternatively, feed 40 to 100 grams of tylosin (1.0 to 2.5 pounds of **Tylan 40**) per ton of complete feed for 2 to 6 weeks immediately after medicating with 250 mg tylosin (as **Tylan Soluble**) per gallon in drinking water for 3 to 10 days. Feed continuously as the sole ration when feeding Tylan.

NOTICE: Organisms vary in their degree of susceptibility to any chemotherapeutic. If no improvement is observed after recommended treatment, diagnosis and susceptibility should be reconfirmed.

| Mixing and Feeding Directions for        | <b>Tylan 40</b> Per Ton Of Type C Feed | Tylosin Per   |
|--|--|---------------|
| Beef Cattle Feeds                        |  | Ton Of Type C |
| For reduction of incidence of liver      |  | Feed          |
| abscesses in beef cattle associated with | 0.2 to 0.25 Ibs                        | 8 to 10 g     |

| Fusobacterium necrophorum and<br>Arcanobacterium pyogenes. | To be fed so that each animal receives not<br>more than 90 mg per head per day and not less<br>than 60 mg per head per day.<br>Feed continuously as the sole ration.   |  |  |  |
|--|--|--|--|--|
| Mixing Directions for Liquid Type B                        | LIMITATIONS:   |  |  |  |
| Cattle Feeds   | 1. pH must be between 4.5 and 6.0.   |  |  |  |
|  | <ol> <li>For liquid feeds stored in recirculating tank systems:<br/>Recirculate immediately prior to use for not less than 10<br/>minutes, moving not less than 1 percent of the tank contents<br/>per minute from the bottom of the tank to the top.<br/>Recirculate daily as described even when not used.</li> <li>For liquid feeds stored in mechanical, air, or other<br/>agitation-type tank system: Agitate immediately prior to<br/>use for not less than 10 minutes, creating a turbulence at<br/>the bottom of the tank that is visible at the top.<br/>Agitate daily as described even when not used.</li> <li>Liquid Type B Cattle Feeds must bear an expiration date<br/>of 31 days after the date of manufacture.</li> </ol> |  |  |  |

#### NOT FOR HUMAN USE

Store at Room Temperature, 25°C (77°F). Avoid moisture.

Not to be used after the date printed on the bottom of the bag.



Principal Display Panel - Tylan 40 Bag Label

Elanco<sup>TM</sup>

AF0040

Tylan™ 40

Net Weight: **50 lbs** (22.68 kg)



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# Tylan 40

Net Weight: 50 lbs

# Tylosin Phosphate

# Type A Medicated Article

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#### For use in Swine and Beef Cattle Feeds Only

#### **Do Not Feed Undiluted**

#### Equivalent to 40 g Tylosin per Pound

#### Swine:

For reduction in severity of effects of atrophic rhinitis.

For control of swine dysentery associated with Brachyspira hyodysenteriae.

For the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae* immediately after medicating with **Tylan Soluble** (tylosin) drinking water.

For control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis*. For control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis* immediately after medicating with **Tylan Soluble** (tylosin) in drinking water.

#### **Beef Cattle:**

For reduction of incidence of liver abscesses associated with Fusobacterium necrophorum and Arcanobacterium pyogenes.

#### Restricted Drug (California), Use only as Directed. Approved by FDA under NADA # 012-491

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Directions for Llee

Read All Directions Carefully

Net Weight: 50 lbs (22.68 kg)

#### Tylan<sup>™</sup> 40 Type A Medicated Article Do Not Feed Undiluted.

Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.

Active Drug Ingredient-Tylosin (as tylosin phosphate) . . . 40 g per lb

Ingredients: Roughage products, calcium carbonate and mineral oil.

Caution: To ensure adequate mixing, an intermediate blending step should be used prior to manufacturing a complete feed. Do not use in any liquid feed containing sodium metabisulfite or in any finished feed (supplement, concentrate or complete feed) containing in excess of 2% bentonite.

Warning: Tylan 40 may be irritating to unprotected skin and eyes. When mixing and handling Tylan 40 use protective clothing, impervious gloves and a dust respirator. In case of accidental eye exposure, flush eyes with plenty of water. Exposed skin should be washed with plenty of soap and water. Remove and wash contaminated clothing. Seek medical attention if irritation becomes severe or persists. The material safety data sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, access medical information, or obtain additional product information, call 1-800-428-4441.

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For control of swine dysentery. Feed 100 g of tylosin per ton (2.5 pounds Tylan 40 per ton) of complete feed for at least three weeks. Follow with 40 g tylosin per ton (1 pound Tylan 40 per ton) of complete feed until pigs reach market weight.

For the treatment and control of swine dysentery. Feed 40 to 100 grams of tylosin (1.0 to 2.5 pounds of Tylan 40) per ton of complete feed for 2 to 6 weeks immediately after medicating with 250 mg tylosin (as Tylan Soluble) per gallon in drinking water for 3 to 10 days.

For control of porcine proliferative enteropathies (PPE, ileitis). Feed 100 g of tylosin per ton (2.5 pounds Tylan 40 per ton) of complete feed for 21 days. Alternatively, feed 100 g of tylosin per ton (2.5 pounds Tylan 40 per ton) of complete feed for at least three weeks, followed by 40 g tylosin per ton of complete feed until pigs reach market weight. Alternatively, feed 40 to 100 grams of tylosin (1.0 to 2.5 pounds of Tylan 40) per ton of complete feed for 2 to 6 weeks immediately after medicating with 250 mg tylosin (as Tylan Soluble) per gallon in drinking water for 3 to 10 days. Feed continuously as the sole ration when feeding Tylan.

NOTICE: Organisms vary in their degree of susceptibility to any chemotherapeutic. If no improvement is observed after recommended treatment, diagnosis and susceptibility should be reconfirmed.

| Mixing and Feeding<br>Directions for<br>Beef Cattle Feeds       | Tylan 40 Per Ton Tylosin Per To<br>Of Type C Feed Of Type C Fe  |           |  |  |  |
|---|---|-----------|--|--|--|
| For reduction of incidence of<br>liver abscesses in beef cattle | 0.2 to 0.25 lbs   | 8 to 10 g |  |  |  |
| Arcanobacterium pyogenes.                                       | To be fed so that each animal receives not more<br>than 90 mg per head per day and not less than<br>60 mg per head per day.<br>Feed continuously as the sole ration.  |           |  |  |  |
| Mixing Directions for   | LIMITATIONS:  |           |  |  |  |
| Liquid Type B<br>Cattle Feeds                                   | 1 pH must be between 4.5 and 6.0.   |           |  |  |  |
|   | <ol> <li>For liquid feeds stored in recirculating tank systems: Recirculate immediately<br/>prior to use for not less than 10 minutes, moving not less than 1 percent of<br/>the tank contents per minute from the bottom of the tank to the top.<br/>Recirculate daily as described even when not used.</li> </ol> |           |  |  |  |
|   | 3. For liquid feeds stored in mechanical, air, or other agitation-type<br>tank system: Agitate immediately prior to use for not less than<br>10 minutes, creating a turbulence at the bottom of the tank that<br>is visible at the top.<br>Agitate daily as described even when not used.                           |           |  |  |  |
|   | <ol> <li>Liquid Type B Cattle Feeds must bear an expiration date of 31 days<br/>after the date of manufacture.</li> </ol>   |           |  |  |  |

#### NOT FOR HUMAN USE

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#### TYLAN 40

| tylosin phosphate granule            |  |                          |                    |  |
|--------------------------------------|--|--------------------------|--------------------|--|
|                                      |  |                          |                    |  |
| Product Information                  |  |                          |                    |  |
| Product Type                         | VFD TYPE A MEDICATED ARTICLE ANIMAL DRUG | Item Code<br>(Source)    | NDC:58198-<br>0040 |  |
| Route of Administration              | ORAL                                     |                          |                    |  |
|                                      |  |                          |                    |  |
|                                      |  |                          |                    |  |
| Active Ingredient/Active Moiety      |  |                          |                    |  |
| Ingredient Name                      |  | <b>Basis of Strength</b> | Strength           |  |
| tylosin phosphate (UNII: NR75X12AFF) | ) (tylosin - UNII:YEF4JXN031)            | tylosin phosphate        | 40 g in 0.45 kg    |  |

Elanco Yuan 40

| Inactive Ingredien      | ts                            |  |               |      |                    |
|-------------------------|-------------------------------|--|---------------|------|--------------------|
|                         | Ingredient Name               |  |               |      | Strength           |
| mineral oil (UNII: T5L8 | Г28 FGP)                      |  |               |      |                    |
| rice bran (UNII: R60QEE | 213IC)                        |  |               |      |                    |
| calcium carbonate (UN   | II: H0 G9 379 FGK)            |  |               |      |                    |
|                         |                               |  |               |      |                    |
|                         |                               |  |               |      |                    |
| Packaging               |                               |  |               |      |                    |
| # Item Code             | Package Description           | Marketii   | ıg Start Date | Μ    | arketing End Date  |
| 1 NDC:58198-0040-1      | 22.68 kg in 1 BAG             |  |               |      |                    |
|                         |                               |  |               |      |                    |
|                         |                               |  |               |      |                    |
| Marketing Information   |                               |  |               |      |                    |
| Marketing Category      | Application Number or Monogra | Application Number or Monograph Citation Marketing Start |               | Date | Marketing End Date |
| NADA                    | NADA0 1249 1                  |  | 0 1/0 8/20 10 |      |                    |
|                         |                               |  |               |      |                    |

# Labeler - Elanco US Inc. (966985624)

### Establishment

| Name                        | Address | ID/FEI    | <b>Business Operations</b> |
|-----------------------------|---------|-----------|----------------------------|
| Elanco Clinton Laboratories |         | 039138631 | API MANUFACTURE            |

## Establishment

| Name                        | Address | ID/FEI    | Business Operations      |
|-----------------------------|---------|-----------|--------------------------|
| Provimi North America, Inc. |         | 027859585 | MANUFACTURE, LABEL, PACK |

Revised: 7/2020

Elanco US Inc.