

**DENAGARD 80 COATED TYPE A MEDICATED ARTICLE- tiamulin fumarate powder**  
**Elanco US Inc.**

-----  
**Net Weight:**  
**55 lb (25 kg)**

**Denagard™ 80%**

**Coated (tiamulin hydrogen fumarate)**

**Type A Medicated Article**

**For the manufacture of Denagard 10  
Type B Medicated Swine Feed only.  
Not to be used for the manufacture of  
Type C medicated feeds.**

**Active Ingredient:**

tiamulin hydrogen fumarate:  
80% w/w (363.2 g/lb.)

**Inactive Ingredients:**

porcine gelatin

**Indications:**

For treatment of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to Tiamulin; For control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis*; For control of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to Tiamulin.

**Warnings:**

Denagard 10 Type B Medicated Swine Feed label contains residue information for use in swine.

Keep out of reach of children.

Irritating to eyes and respiratory system.

May cause sensitization by inhalation and skin contact. Do not breathe dust.

Avoid contact with skin and eyes.

Wear suitable protective clothing and gloves.

**Caution:**

Do not feed undiluted. Do not use in feeds for animals other than swine. The effects of tiamulin on swine reproductive performance, pregnancy and lactation have not been determined. Swine being treated with Denagard (tiamulin) should not have access to feeds containing polyether ionophores (e.g., lasalocid, monensin, narasin, salinomycin and semduramicin) as adverse reactions may occur. If signs of toxicity occur, discontinue use.

**Storage:**

**Protect from light and moisture. Store at or below 25°C (77°F). Temporary excursions to 40°C (104°F) permitted.**

**Directions For Preparation of Denagard 10 Type B Medicated Swine Feed.**

<b>Ingredient:</b>	Denagard 80% Coated (tiamulin hydrogen fumarate)	Rice Hulls	Mineral Oil
<b>Quantity per 2000 lbs.:</b>	56.2 lbs.*	1863.8 lbs.	80 lbs.

With mixer on, dispense mineral oil into rice hulls. Mix until sufficiently blended. Add Denagard 80% Coated (tiamulin hydrogen fumarate) to mixture while mixer is running. Mix until homogeneous.

\* Includes 2% overage.

**Restricted Drug (California):  
Use only as directed.**

For more information or to report adverse effects, call Elanco US Inc. at 1-800-428-4441.

For a complete listing of adverse reactions for DENAGARD reported to CVM see: [www.fda.gov/reportanimalae](http://www.fda.gov/reportanimalae)

**Manufactured for:  
Elanco US Inc.  
Greenfield, IN 46140 USA**

**Product of Italy  
Product of China**

Lot Number:

Date of  
Manufacture:

Date of  
Expiration:

Denagard, Elanco and the diagonal bar logo are trademarks of Elanco or its affiliates.  
© 2023 Elanco or its affiliates

© 2021 Elanco or its affiliates

Approved by FDA under NADA # 139-472

YL240600X

YL230102A

**Elanco™**

**Principal Display Panel - 22 g in 1 kg Bag Label**

**Net Weight:**

**55 lb (25 kg)**

**Denagard™ 80%**

**Coated (tiamulin hydrogen fumarate)**

**Type A Medicated Article**

**Approved by FDA under NADA # 139-472**

**Net Weight:**  
**55 lb (25 kg)**

# Denagard™ 80%

## Coated (tiamulin hydrogen fumarate)



### Type A Medicated Article

For the manufacture of Denagard 10  
**Type B Medicated Swine Feed only.**  
Not to be used for the manufacture of  
**Type C medicated feeds.**

**Active Ingredient:**  
tiamulin hydrogen fumarate:  
80% w/w (363.2 g/lb.)

**Inactive Ingredients:**  
porcine gelatin

**Indications:**  
For treatment of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to Tiamulin; For control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis*; For control of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to Tiamulin.

**Warnings:**  
Denagard 10 Type B Medicated Swine Feed label contains residue information for use in swine.

Keep out of reach of children.  
Irritating to eyes and respiratory system.  
May cause sensitization by inhalation and skin contact. Do not breathe dust.  
Avoid contact with skin and eyes.  
Wear suitable protective clothing and gloves.

**Caution:**  
Do not feed undiluted. Do not use in feeds for animals other than swine. The effects of tiamulin on swine reproductive performance, pregnancy and lactation have not been determined. Swine being treated with Denagard (tiamulin) should not have access to feeds containing polyether ionophores (e.g., lasalocid,

monensin, narasin, salinomycin and semduramicin) as adverse reactions may occur. If signs of toxicity occur, discontinue use.

**Storage:**  
Protect from light and moisture. Store at or below 25°C (77°F). Temporary excursions to 40°C (104°F) permitted.

**Directions for Preparation of Denagard 10 Type B Medicated Swine Feed.**

Ingredient:	Denagard 80% Coated (tiamulin hydrogen fumarate)	Rice Hulls	Mineral Oil
Quantity per 2000 lbs.:	56.2 lbs.*	1863.8 lbs.	80 lbs.

With mixer on, dispense mineral oil into rice hulls. Mix until sufficiently blended. Add Denagard 80% Coated (tiamulin hydrogen fumarate) to mixture while mixer is running. Mix until homogeneous.

\* Includes 2% overage.

**Restricted Drug (California):**  
**Use only as directed.**

For more information or to report adverse effects, call Elanco US Inc. at 1-800-428-4441.

For a complete listing of adverse reactions for DENAGARD reported to CVM see: [www.fda.gov/reportanimalae](http://www.fda.gov/reportanimalae)

**Manufactured for:**  
**Elanco US Inc.**  
**Greenfield, IN 46140 USA**

**Product of Italy**

Denagard, Elanco and the diagonal bar logo are trademarks of Elanco or its affiliates.  
© 2023 Elanco or its affiliates

Approved by FDA under NADA # 139-472

Lot Number:

Date of  
Manufacture:

Date of  
Expiration:

YL240600X



**Net Weight:**

**55 lb (25 kg)**

**Denagard™ 80%**

**Coated (tiamulin hydrogen fumarate)**

**Type A Medicated Article**

**Approved by FDA under NADA # 139-472**

Net Weight:  
55 lb (25 kg)

# Denagard™ 80%

## Coated (tiamulin hydrogen fumarate)



### Type A Medicated Article

For the manufacture of Denagard 10  
Type B Medicated Swine Feed only.  
Not to be used for the manufacture of  
Type C medicated feeds.

**Active Ingredient:**  
tiamulin hydrogen fumarate:  
80% w/w (363.2 g/lb.)

**Inactive Ingredients:**  
porcine gelatin

**Indications:**  
For treatment of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to Tiamulin; For control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis*; For control of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to Tiamulin.

**Warnings:**  
Denagard 10 Type B Medicated Swine Feed label contains residue information for use in swine. ◀  
Keep out of reach of children.  
Irritating to eyes and respiratory system.  
May cause sensitization by inhalation and skin contact. Do not breathe dust.  
Avoid contact with skin and eyes.  
Wear suitable protective clothing and gloves.

**Caution:**  
Do not feed undiluted. Do not use in feeds for animals other than swine. The effects of tiamulin on swine reproductive performance, pregnancy and lactation have not been determined. Swine being treated with Denagard (tiamulin) should not have access to feeds containing polyether ionophores (e.g., lasalocid,

monensin, narasin, salinomycin and semduramicin) as adverse reactions may occur. If signs of toxicity occur, discontinue use.

**Storage:**  
Protect from light and moisture. Store at or below 25°C (77°F). Temporary excursions to 40°C (104°F) permitted.

**Directions For Preparation of Denagard 10 Type B Medicated Swine Feed.**

Ingredient:	Denagard 80% Coated (tiamulin hydrogen fumarate)	Rice Hulls	Mineral Oil
Quantity per 2000 lbs.:	56.2 lbs.*	1863.8 lbs.	80 lbs.

With mixer on, dispense mineral oil into rice hulls. Mix until sufficiently blended. Add Denagard 80% Coated (tiamulin hydrogen fumarate) to mixture while mixer is running. Mix until homogeneous.

\* Includes 2% overage.

**Restricted Drug (California):**  
Use only as directed.

For more information or to report adverse effects, call Elanco US Inc. at 1-800-428-4441.

For a complete listing of adverse reactions for DENAGARD reported to CVM see: [www.fda.gov/reportanimalae](http://www.fda.gov/reportanimalae)

**Manufactured for:**  
**Elanco US Inc.**  
**Greenfield, IN 46140 USA**

**Product of China**

Denagard, Elanco and the diagonal bar logo are trademarks of Elanco or its affiliates.  
© 2021 Elanco or its affiliates

Approved by FDA under NADA # 139-472

Lot Number:

Date of  
Manufacture:

Date of  
Expiration:

YL230102A



**DENAGARD 80 COATED TYPE A MEDICATED ARTICLE**

tiamulin fumarate powder

### Product Information

<b>Product Type</b>	OTC ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:58198-9413
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Tiamulin Fumarate</b> (UNII: ION1Q02ZCX) (Tiamulin - UNII:E38WZ4U54R)	Tiamulin Fumarate	22 g in 1 kg

### Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:58198-9413-1	25 kg in 1 BAG		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
NADA	NADA139472	11/01/2015	

**Labeler** - Elanco US Inc. (966985624)

Revised: 11/2025

Elanco US Inc.