

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.

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

Manufactured for:

Elanco US Inc.

Greenfield, IN 46140 USA

Product of Italy

Lot Number:

Date of

Manufacture:

Date of

Expiration:

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Approved by FDA under NADA # 139-472

YL240600X

Elanco™

Principal Display Panel - 22 g in 1 kg Bag Label

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DENAGARD 80 COATED TYPE A MEDICATED ARTICLE

tiamulin fumarate powder

Product Information

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

Active Ingredient/Active Moiety

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

Packaging

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

Marketing Information

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

Labeler - Elanco US Inc. (966985624)

Revised: 9/2023

Elanco US Inc.