

SULFADIMETHOXINE CONCENTRATED SOLUTION 12.5%- sulfadimethoxine concentrated solution 12.5% solution
Cronus Pharma LLC

Sulfadimethoxine Concentrated Solution 12.5%

NDC: 69043-025-89

Sulfadimethoxine Concentrated Solution 12.5%

ANTIBACTERIAL

for Use in Drinking Water

For Oral Use in Chickens, Turkeys, and Cattle

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Approved by FDA under ANADA # 200-165

PROTECT FROM LIGHT

NET CONTENTS: 1 Gallon (3.785 L)

INDICATIONS

BROILER AND REPLACEMENT CHICKENS: Use for the treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza.

MEAT PRODUCING TURKEYS: Use for the treatment of disease outbreaks of coccidiosis and fowl cholera.

DAIRY CALVES, DAIRY HEIFERS AND BEEF CATTLE: Use for the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella spp.* sensitive to sulfadimethoxine, calf diphtheria and foot rot associated with *Fusobacterium necrophorum* (*Sphaerophorus necrophorus*) sensitive to sulfadimethoxine.

PRECAUTIONS

Store at controlled room temperature 20° to 25°C (68° to 77°F), excursions permitted from 15° to 30°C (59° to 86°F). If freezing occurs, thaw before using. Protect from light; direct sunlight may cause discoloration. Freezing or discoloration does not affect potency. Prepare a fresh stock solution daily.

CHICKENS AND TURKEYS: If animals show no improvement within 5 days, discontinue treatment and re-evaluate diagnosis. Handle the recommended dilutions (chickens 0.05% and turkeys 0.025%) as regular drinking water. Administer as sole source of drinking water and sulfonamide medication.

Chickens and turkeys that have survived fowl cholera outbreaks should not be kept for replacements or breeders.

CATTLE: During treatment period, make certain that animals maintain adequate water intake. If animals show no improvement within 2 or 3 days, re-evaluate diagnosis. Treatment should not be continued beyond 5 days.

FOR USE IN ANIMALS ONLY

NOT FOR USE IN HUMANS

KEEP OUT OF REACH OF CHILDREN



RESIDUE WARNINGS

Chickens and Turkeys - Withdraw 5 days before slaughter. Do not administer to chickens over 16 weeks (112 days) of age or to turkeys over 24 weeks (168 days) of age.

Cattle - Withdraw 7 days before slaughter. For dairy calves, dairy heifers and beef cattle only.

A withdrawal period has not been established for this product in pre-ruminating calves.

Do Not Use in Calves to be Processed for Veal

Restricted Drug (California) - Use Only as Directed

DO NOT SLAUGHTER COW FOR 7 DAYS AFTER LAST TREATMENT

Dosage and Administration

Chickens and Turkeys

Treatment Period: 6 consecutive days

Recommended Concentrations: Chickens - 0.05%; Turkeys - 0.025%

Chickens Add 1 fl oz (30 mL) to 2 gallons of drinking water or 25 fl oz to 50 gallons of drinking water.

Turkeys Add 1 fl oz (30 mL) to 4 gallons of drinking water or 25 fl oz to 100 gallons of drinking water.

Automatic To make 2 gallons of Stock Solution use:

Proportioners* Stock Solution

Chickens Add 1 gallon of Sulfadimethoxine Concentrated Solution 12.5% to 1 gallon of water

Turkeys Add 2 qts of Sulfadimethoxine Concentrated Solution 12.5% to 6 qts of water

*Set proportioner to a feed rate of 1 fl oz (30 mL) of Sulfadimethoxine Stock Solution per gallon of water.

Dairy Calves, Dairy Heifers, and Beef Cattle

Treatment Period: 5 consecutive days

Dosage: Initial dose of 25 mg/lb followed by four maintenance doses of 12.5 mg/lb/day

Summer Administration

Dosage recommendations for summer are based on an estimated water intake of 1 gallon of water per every 100 lb of body weight per day.

Sulfadimethoxine Concentrated Solution 12.5%

Daily Drinking Water Initial Dose Maintenance Dose

Supply

25 gal	1 pt (16 fl oz)	1 cup (8 fl oz)
50 gal	1 qt (32 fl oz)	1 pt (16 fl oz)
200 gal	1 gal (128 fl oz)	2 qt (64 fl oz)

Winter Administration

Dosage recommendations for winter are based on an estimated water intake of 1 gallon of water per every 150 lb of body weight per day.

Sulfadimethoxine Concentrated Solution 12.5%

Daily Drinking Water Initial Dose Maintenance Dose

Supply

16 gal	1 pt (16 fl oz)	1 cup (8 fl oz)
33 gal	1 qt (32 fl oz)	1 pt (16 fl oz)
127 gal	1 gal (128 fl oz)	2 qt (64 fl oz)

For individual treatment of cattle, Sulfadimethoxine Concentrated Solution 12.5% may be given as a drench. Administer using an initial dose of 25 mg/lb followed by 4 maintenance doses of 12.5 mg/lb/day. One fl oz will medicate one 150-lb animal initially and 1/2 fl oz will medicate one 150-lb animal on maintenance dose.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

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 CATTLE: During treatment period, make certain that animals maintain adequate water intake. If animals show no improvement within 2 or 3 days, re-evaluate diagnosis. Treatment should not be continued beyond 5 days.

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 for Use in Drinking Water

For Oral Use in Chickens, Turkeys, and Cattle

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NET CONTENTS: 1 GALLON (3.785 liters)

PROTECT FROM LIGHT



3.75 g sulfadimethoxine/fl oz.
Dosage and Administration

Chickens and Turkeys

Treatment Period: 6 consecutive days
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Chickens Add 1 fl oz (30 mL) to 2 gallons of drinking water-or- 25 fl oz to 50 gallons of drinking water.
Turkeys Add 1 fl oz (30 mL) to 4 gallons of drinking water-or- 25 fl oz to 100 gallons of drinking water.

Automatic Proportioners* Stock Solution – To make 2 gallons of Stock Solution use:
Chickens Add 1 gallon of Sulfadimethoxine Concentrated Solution 12.5% to 1 gallon of water
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Treatment Period: 5 consecutive days
Dosage: Initial dose of 25 mg/lb followed by four maintenance doses of 12.5 mg/lb/day

Summer Administration
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Daily Drinking Water Supply	Sulfadimethoxine Concentrated Solution 12.5%	
	Initial Dose	Maintenance Dose
25 gal	1 pt (16 fl oz)	1 cup (8 fl oz)
50 gal	1 qt (32 fl oz)	1 pt (16 fl oz)
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DO NOT SLAUGHTER COW FOR 7 DAYS AFTER LAST TREATMENT

Manufactured for:
 Cronus Pharma LLC,
 East Brunswick, NJ 08816
 Contact No.: 1-844-227-6687
 (1-844-2-CRONUS) S: 2766-07 Rev. 04-20

Lot No.: Exp. Date:

SULFADIMETHOXINE CONCENTRATED SOLUTION 12.5%

sulfadimethoxine concentrated solution 12.5% solution

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:69043-025
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sulfadimethoxine (UNII: 30CPC5LDEX) (SULFADIMETHOXINE - UNII:30CPC5LDEX)	Sulfadimethoxine	125 mg in 1 mL

Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69043-025-89	3785 mL in 1 JUG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200165	12/12/2022	

Labeler - Cronus Pharma LLC (079421067)

Revised: 9/2023

Cronus Pharma LLC