# SULFADIMETHOXINE CONCENTRATED SOLUTION 12.5%- sulfadimethoxine concentrated solution 12.5% solution Aspen Veterinary Resources Ltd

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#### Sulfadimethoxine Concentrated Solution 12.5%

NDC: 46066-081-11

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 ats 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%**

# <u>Daily Drinking Water</u> <u>Initial Dose Maintenance Dose</u>

**Supply** 

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

# <u>Daily Drinking Water</u> <u>Initial Dose Maintenance Dose</u> <u>Supply</u>

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



#### **SULFADIMETHOXINE CONCENTRATED SOLUTION 12.5%**

sulfadimethoxine concentrated solution 12.5% solution

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Product Type PRESCRIPTION ANIMAL DRUG Item Code (Source) NDC:46066-081

**Route of Administration** ORAL

#### **Active Ingredient/Active Moiety**

Active ingredient/Active Projecty			
Ingredient Name	Basis of Strength	Strength	
<b>Sulfadimethoxine</b> (UNII: 30CPC5LDEX) (SULFADIMETHOXINE - UNII: 30CPC5LDEX)	Sulfadimethoxine	125 mg in 1 mL	

## **Product Characteristics**

Color	yellow	Score
Shape		Size
Flavor		Imprint Code
Contains		

#### **Packaging**

3 3					
	#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
	1 NE	C:46066-081-11	3785 mL in 1 JUG		

### **Marketing Information**

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

# Labeler - Aspen Veterinary Resources Ltd (627265361)

Revised: 12/2022 Aspen Veterinary Resources Ltd