

SULFORAL- sulfadimethoxine oral solution solution
Med-Pharmex, Inc

Sulforal(sulfadimethoxine)Antibacterial

NDC 54925-034-11

Protect From Light

Antibacterial for use in drinking water

Concentrated Solution 12.5%

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

3.75g sulfadimethoxine/fl.oz.

For oral use in chickens, turkeys, and cattle

1 Gallon (3.8L)

MED-PHARMEX

INCORPORATED

Pomona, CA 91767

ANADA #200-251

Approved BY FDA

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; and calf diphtheria and foot rot associated with *Fusobacterium necrophorum* (*Sphaerophorus necrophorus*) sensitive to sulfadimethoxine.

CAUTION: Store at room temperature; 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 reevaluate diagnosis. Handle the recommended dilutions (chickens 0.05% and turkeys 0.0.25%) 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, reevaluate diagnosis. Treatment should not be continued beyond 5 days.

Restricted Drug (California) - Use Only as Directed. Not for Human Use.

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 preruminating calves.

Do Not Use in Calves to be Processed For Veal

Store at Controlled Room Temperature 15°-30°C (59°-86°F)

DO NOT SLAUGHTER COW FOR 7 DAYS AFTER LAST TREATMENT

Dosage and Administration:

Chickens and Turkeys		
Treatment Period: 6 consecutive days		
Recommended Concentration: Chickens -0.05%; Turkeys -0.025%		
Chickens Add 1 fl oz (30 mL) to 2 gal of drinking water or 25 fl oz to 50 gal of drinking water.		
Turkeys Add 1 fl oz (30 mL) 4 gal of drinking water or 25 fl oz to 100 gal of drinking water.		
Automatic Proportioners* Stock Solution - To make 2 gal of stock solution:		
Chickens Add 1 gal of Sulforal Concentrated Solution 12.5% to 1gal of water.		
Turkeys Add 2 qt of Sulforal Concentrated Solution 12.5% to 6 qt of water.		
*Set proportioner to a feed rate of 1 fl oz of stock solution per gal of water		
Dairy Calvers, Dairy Heifers and Beef Cattle		
Treatment Period: 5 consecutive days		
Dosage: Initial dose of 25 mg/lb followed by four maintenance dose of 12.5 mg/lb/day.		
Summer Administration		
Dosage recommendations for summer are based on an estimated water intake of 1 gal of water for every 100 lb of body weight per day.		
Sulfadimethoxine Concentrated Solution 12.5%		
Daily Drinking Water Supply	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)
200 gal	1 gal (128 fl oz)	2 qt (64 fl oz)
Winter Administration		
Dosage recommendations for summer are based on an estimated water intake of 1 gal of water for every 150 lb of body weight per day.		
Sulfadimethoxine Concentrated Solution 12.5%		
Daily Drinking Water Supply	Initial Dose	Maintenance Dose
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 medicated one 150-lb animal initially and 1/2 fl oz will medicate one 150-lb animal on maintenance dose.		
Lot # / Exp.Date		

ACTIVE DRUG INGREDIENT: Sulfadimethoxine.
INACTIVE DRUG INGREDIENTS: Disodium Edetate, Sodium Bisulfite, Sodium Hydroxide, Purified Water QS.

Caution: Store at room temperature; 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.

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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, reevaluate diagnosis. Treatment should not be continued beyond 5 days.

Restricted Drug (California) - Use Only as Directed.
 Not for Human Use.

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.

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

Do Not Use in Calves to be Processed For Veal.

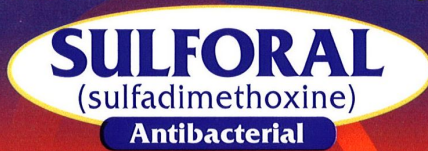
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 AFTER LAST TREATMENT



NDC 54925-034-11

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Antibacterial for use in drinking water
CONCENTRATED SOLUTION 12.5%

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1 Gallon (3.8 L)



ANADA #200-251 APPROVED BY FDA

REV. 6/16

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Chickens and Turkeys

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Chickens Add 1 fl oz (30 mL) to 2 gal of drinking water or

25 fl oz to 100 gal of drinking water.

Turkeys Add 1 fl oz (30 mL) to 4 gal of drinking water or

25 fl oz to 100 gal of drinking water.

Automatic Proportioners* Stock Solution – To make 2 gal of stock solution:

Chickens Add 1 gal of Sulfadimethoxine Concentrated Solution 12.5% to 1 gal of water.

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

*Set proportioner to a feed rate of 1 fl oz of stock solution per gal 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 gal of water for every 100 lb of body weight per day

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)
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 gal of water for every 150 lb of body weight per day

Daily Drinking Water Supply	Sulfadimethoxine Concentrated Solution 12.5%	
	Initial Dose	Maintenance Dose
16 gal	1 pt (16 fl oz)	1 cup (8 fl oz)
33 gal	1 qt (32 fl oz)	1 pt (16 fl oz)
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Lot # / Exp. Date

SULFORAL

sulfadimethoxine oral solution solution

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:54925-034
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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54925-034-11	3785 mL in 1 JUG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200251	09/01/2011	

Labeler - Med-Pharmex, Inc (025353699)

