

SULFADIMETHOXINE CONCENTRATED SOLUTION 12.5%- sulfadimethoxine solution 12.5% solution, concentrate
Aspen Veterinary Resources, Ltd

Sulfadimethoxine 12.5%

(sulfadimethoxine)

CONCENTRATED SOLUTION 12.5%

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

Antibacterial for use in drinking water

For Oral Use in Chickens, Turkeys and Cattle

3.75 g sulfadimethoxine/fl oz

Protect From Light

Approved by FDA under ANADA # 200-030

NET CONTENTS:

3.8 L

(1 GALLON)

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.

PRECAUTION: 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 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.

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.

STORE AT CONTROLLED ROOM TEMPERATURE 20-25°C (68-77°F).

NOT FOR USE IN HUMANS

KEEP OUT OF REACH OF CHILDREN

Restricted Drug (California) - Use Only as Directed

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Huvepharma, Inc. at 1-877-994-4883 or www.huvepharma.us. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>.

Manufactured for:

Aspen Veterinary Resources®, Ltd.

Liberty, MO 64068

www.aspenveterinaryresources.com



LOT NO.:

EXP. DATE:

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.

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

Turkeys

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.

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

Turkeys

*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

25 gal
50 gal
200 gal

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

16 gal
33 gal
127 gal

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 ½ fl oz will medicate one 150-lb animal on maintenance dose.

Sulfadimethoxine Concentrated Solution 12.5%

Initial Dose

1 pt (16 fl oz)
1 qt (32 fl oz)
1 gal (128 fl oz)

Maintenance Dose

1 cup (8 fl oz)
1 pt (16 fl oz)
2 qt (64 fl oz)

Sulfadimethoxine Concentrated Solution 12.5%

Initial Dose

1 pt (16 fl oz)
1 qt (32 fl oz)
1 gal (128 fl oz)

Maintenance Dose

1 cup (8 fl oz)
1 pt (16 fl oz)
2 qt (64 fl oz)

INDICATIONS:
BROILER AND REPLACEMENT CHICKENS – Use for the treatment of disease outbreaks of coccidiosis, foot chloera, and infectious conjunctivitis.
MEAT PRODUCING TURKEYS – Use for the treatment of disease outbreaks of coccidiosis and foot chloera.
DAIRY CALVES, DAIRY HEIFERS AND BEEF CATTLE – Use for the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella sp.* sensitive to sulfadimethoxine and calf diptheria and foot rot associated with *Fusobacterium necrophorum* (Epitheliphthora necrophorum) sensitive to sulfadimethoxine.

PRECAUTIONS: 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 re-evaluate diagnosis. Handle the recommended dilutions (chickens 0.05% and turkeys 0.25%) as regular drinking water. Administer as sole source of drinking water and sulfonamide medication. Chickens and turkeys that have survived foot chloera 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.

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.

STORE AT CONTROLLED ROOM TEMPERATURE 20-25°C (68-77°F).
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KEEP OUT OF REACH OF CHILDREN
Restricted Drug (California) – Use Only as Directed
 To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Hoeprharm, Inc. at 1-877-994-8885 or www.hoeprharm.com. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VE15 or http://www.fda.gov/report-drugad.

Manufactured for:
 Aspen Veterinary Resources*, Ltd.
 Liberty, MO 64068
 www.aspenveterinaryresources.com

LOT NO.: _____ EXP. DATE: _____

NDC 46066-555-93

Sulfadimethoxine 12.5%
 (sulfadimethoxine)
 CONCENTRATED SOLUTION 12.5%

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.
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3.75 g sulfadimethoxine/fl oz
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Approved by FDA under ANADA # 200-030
 NET CONTENTS:
 3.8 L
 (1 GALLON)


Dosage and Administration
Chickens and Turkeys
Treatment Period: 6 consecutive days
Recommended Concentration: Chickens – 0.05%; Turkeys – 0.25%
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) to 4 gal of drinking water or 25 fl oz to 100 gal of drinking water.
Automatic Proportions* 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
15 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 ½ fl oz will medicate one 150-lb animal on maintenance dose.



SULFADIMETHOXINE CONCENTRATED SOLUTION 12.5%

sulfadimethoxine solution 12.5% solution, concentrate

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:46066-555
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sulfadimethoxine (UNII: 30CPC5LDEX) (SULFADIMETHOXINE - UNII:30CPC5LDEX)	Sulfadimethoxine	3750 mg in 0.2366 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46066-555-93	3.8 L in 1 JUG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200030	01/30/2019	

Labeler - Aspen Veterinary Resources, Ltd (627265361)

Revised: 6/2023

Aspen Veterinary Resources, Ltd