

**DI-METHOX CONCENTRATED SOLUTION 12.5%- sulfadimethoxine
concentrated solution 12.5% solution, concentrate
Huvepharma, Inc**

**DI-METHOX®
(sulfadimethoxine)
CONCENTRATED SOLUTION 12.5%**

NDC 23243-370-07

**DI-METHOX®
(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 Liters (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>.

S-3369-07

Rev. 03-2021

TAKE TIME



OBSERVE LABEL
DIRECTIONS

Manufactured for
Huvepharma, Inc.
Peachtree City, GA 30269

® Registered trademark of Huvepharma, Inc.

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.

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 DiMethox® Concentrated Solution 12.5% to 1 gal of water.

Turkeys Add 2 qt of DiMethox® 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.

DiMethox® 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 winter are based on an estimated water intake of 1 gal of water for every 150 lb of body weight per day.

DiMethox® 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, Di-Methox® 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.

INDICATIONS:
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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 diptheria and foot rot associated with *Pseudomonas necrophorum* (*Sphaerophorus necrophorus*) sensitive to sulfadimethoxine.

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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.

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.

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NET CONTENTS: 3.8 Liters (1 GALLON)



Dosage and Administration
Chickens and Turkeys
Treatment Period: 6 consecutive days
Recommended Concentration: Chickens—0.05%, Turkeys—0.025%
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Automatic Proportioner* Stock Solution—To make 2 gal of stock solution:
Chickens Add 1 gal of DiMethox® Concentrated Solution 12.5% to 1 gal of water.
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 *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

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 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	DiMethox® Concentrated Solution 12.5%	
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Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:23243-3700
Route of Administration	Oral		

Active Ingredient/Active Moiety

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

UNII:30CPC5LDEX)	Sulfamethoxine	in 0.2366 L		
Inactive Ingredients				
Ingredient Name		Strength		
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
HYDROCHLORIC ACID (UNII: QTT17582CB)				
SODIUM METABISULFITE (UNII: 4VON5FNS3C)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23243-3700-7	3.8 L in 1 JUG		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANADA	ANADA200030	02/01/2009		

Labeler - Huvepharma, Inc (619153559)

Registrant - Huvepharma EOOD (552671651)

Establishment			
Name	Address	ID/FEI	Business Operations
Sparhawk Laboratories, Inc.		147979082	manufacture, analysis

Revised: 3/2023

Huvepharma, Inc