SULFASOL - sulfadimethoxine sodium powder, for solution Dechra Veterinary Products

SULFASOL SOLUBLE POWDER

(Brand of Sulfadimethoxine)

Antibacterial

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

Approved by FDA under ANADA #200-238

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

Net Wt.: 3.77 oz (107g)

Each packet contains 3.34 oz. (94.6 g) sulfadimethoxine in the form of the soluble sodium salt and disodium edetate.

INDICATIONS FOR USE:

For Broiler and Replacement Chickens Only - Use for the treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza.

For Meat-producing Turkeys Only - Use for the treatment of disease outbreaks of coccidiosis, and fowl cholera.

For 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 *Sphaerophorus necrophorus* sensitive to sulfadimethoxine.

	รเ	ULFADIMETHOXINE			
	SC	OLUBLE POWDER			
Dosage and Admi	inistration:				
Species	Concentration	Use of Directions			
Chickens	0.050%	Contents of packet to 50 gal of water			
Turkeys	0.025%	Contents of packet to 100 gal of water			
rate of 1 fl oz stock Treatment Perioc	solution per gal of water. 1: 6 consecutive days				
	ry Heifers, and Beef Ca				
Dosage: 25 mg/lb [•]	first day followed by 12.5				
	S	Sulfadimethoxine in Water			
	M	Water Consumption			
		Summer)* (Winter)* L gal/100 lb body 1 gal/150 lb body weight** weight**			

First Day	1 qt	10 gal	7 gal
Add	2 qt	20 gal	14 gal
	1 gal	40 gal	28 gal
Next 4 Day	s 1 qt	20 gal	14 gal
Add	2 qt	40 gal	28 gal
	1 gal	80 gal	56 gal

***Note:** Make a cattle stock solution by adding 1 packet of Sulfadimethoxine Soluble Powder to 1 gal of water.

*Twenty fl oz of cattle stock solution will medicate 1-600 lb animal initially or 2-600 lb animals on maintenance dose. Contents of packet will medicate 6-600 lb animals initially or 12-600 lb animals on maintenance dose.

**This dosage recommendation is based on a water consumption of 1 gal per 100 lb of body weight per day, the expected water consumption rate for summer. Water consumption during cold months (winter) may drop markedly (30%-40%). Accordingly, adjustments must be made in the dilution rates to compensate for this and insure proper drug intake.

For treatment of individual cattle, Sulfadimethoxine Soluble Powder stock solution for cattle may be given as a drench.

Treatment Period: 5 consecutive days

CAUTION:

Chickens and Turkeys - If animals show no improvement within 5 days, discontinue treatment and reevaluate diagnosis. Prepare a fresh stock solution daily. 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, reevaluate diagnosis. Treatment should not be continued beyond 5 days.

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

CONTACT INFORMATION: To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Dechra at (866) 933-2472. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at http://www.fda.gov/reportanimalae

SULFASOL is a trademark of Med-Pharmex, Inc.

Manufactured for:

Dechra Veterinary Products, LLC Overland Park, KS 66211

Rev. 05/2023

SULFADIMETHOXINE NDC 17033-428-03 SOLUBLE POWDER Use of Directions Contents of packet to 50 gal of wate 0.025% Contents of packet to 100 gal of water Contents of packet to 100 gal of water **SULFASOL**[™] Automatic Propertioners: To make stock solution, add contents of 5 packets to 2 gal of water for chickens and to 4 gal of water for turkeys. Set proportioner to teed at a rate of 1 fi oz stock solution per gal of water. Treatment Perturb. 6 consecutive days Dairy Calves, Dairy Helfers, and Beef Cattle Dosege: 25 mg/b first day followed by 12.5 mg/b/day for 4 days (sulfadimethoxine) Sulfadimethosine in Water Water Consumption Amount of Stock (Summer)* 1 gal/100 lb Wister)* I gal/150 lb olution for Cattle 1 gal/150 ta body weight 7 gal 14 gal 28 gal 14 gal 28 gal 56 gal 56 gal body weight* 10 gal 20 gal 40 gal Antibacterial First flav Add 1 of SOLUBLE POWDER Next 4 Days Add 40 gal 80 gal 1 gal CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Each packet contains 3.34 oz. (94.6 g) sulfadimethoxine in the form of the soluble sodium salt and disodium edetate. entrant of individual cattle, Suffactimethosine Soluble Powder stock solution for cattle may be given as a de ent Period: 5 consecutive days Restricted Drug (California) - Use Only as Directed. Not for Use in Humans. Intent Pariod-5 consecutive days to crickless are findely on the intervention of the processment within 5 days, discontinues heartness and use seeds. Preserve in tests darks readow raily, handle the recommended devices yets and use the set of the process of the pro-tanting the three survived box includes a contravision standard and be legit or explacements or technicals on the user standard box in the process of the overlands within 2 or 3 days, remediate days reads within a terminal standard box in the process of the process of the process of the process of the overlands within 2 or 3 days, remediate days reads. For Broiler and Replacement Chickens Only - Use for the treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza. For Meat-producing Turkeys Only - Use for the treatment of disease outbreaks of coccidiosis, and fowl cholera. show no For Dairy Calves, Dairy Helfers, and Beef Cattle - Use for the treatment of shipping fever Wanning: Chickens and Tarkeys - Withdow 5 days before staughter. On not administer to chickens over 19 weeks (112 days) of oge or to barkeys over 24 weeks (168 days) of age. Cattle - Withdow 7 days before staughter. For days overs, dary hefters and beef cattle org. A withdower generation for not been existinged for this product in po-turnisting calw to the target of the Processing For Web complex and bacterial pneumonia associated with Pasteurella spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with Sphaerophorus necrophorus sensitive to sulfadimethoxine. Approved by FDA under ANADA # 200-238 CONTACT INFORMATION: To report suspected advarse drug events, for factorical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Declara at 1) 933-2472 (969) 652-2472. The additional information about adverse image experience reporting for animal drugs, contact FDA at 1-689-FDA-VETS or online at 11tb;//www.fBc.gov/reportanimalae SILEMASDL is a trademark of Mod-Pharmon, Inc. MANEWFORTBED FOR: Dectras Septimary Products, Overland Park, KS 06211 USA Dechra Net Wt.: 3.77 oz (107g) Rev. April 2023

SULFASOL

sulfadimethoxine sodium powder, for solution

Product Information							
Product Type		PRESCRIPTION ANIM	AL DRUG	ltem Co	de (Soui	r ce) NE	DC:17033-428
Route of Administra	tion	ORAL					
Active Ingredient/Active Moiety							
Ingredient Name Basis of Strength Strength							
SULFADIMETHOXINE SODIUM (UNII: 49DG2B481W) (SULFADIMETHOXINE - SULFADIMETHOXINE - UNII: 30CPC5LDEX)			ETHOXINE	94.6 g in 107 g			
Packaging							
	Packa	ge Description	Marketin	g Start	Date	Marketin	g End Date
# Item Code	Facka	9					
	107 g in 1	-					
		-					

ANADA ANADA200238 05/17/2023	Marketing	Application Number or Monograph	Marketing Start	Marketing End
	Category	Citation	Date	Date
	ANADA	ANADA200238	05/17/2023	

Labeler - Dechra Veterinary Products (362142734)

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