SULFASOL - sulfadimethoxine sodium powder, for solution Med-Pharmex, Inc

SULFASOL SOLUBLE POWDER

(sulfadimethoxine) **Antibacterial**

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

Approved by FDA under ANADA #200-238

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

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

Net Wt.: 3.77 oz (107g)

| | SULFADIMETHOXINE | | | | | | | |
|-------------------|---------------------------------|----------------|------------------|---------------------------------|--|--|--|--|
| | SOLUBLE POWDER | | | | | | | |
| Dosage and | d Administrati | on: | | | | | | |
| Species | Concentration Use of Directions | | | | | | | |
| Chickens | | 0.05% | | Contents of packet to 50 gal | | | | |
| | | | | of water | | | | |
| Turkeys | | 0.025% | | Contents of packet to 100 gal | | | | |
| | | | | of water | | | | |
| | | | | l contents of 5 packets to 2 ga | | | | |
| of water for | chickens and to | 4 gal of water | r for turkeys. S | et proportioner to feed at a | | | | |
| | z stock solution | | | | | | | |
| Treatment | Period: 6 con | secutive day | S | | | | | |
| Dairy Calve | s, Dairy Heife | rs, and Beef | Cattle | | | | | |
| Dosage: 25 | mg/lb first day | followed by 12 | 2.5 mg/lb/day fo | or 4 days | | | | |
| | | | Sulfadimeth | oxine in Water | | | | |
| | | | Water Cons | umption | | | | |
| | Amount of S | Stock Solutio | n(Summer)* | (Winter)* | | | | |
| | for Cattle* | | 1 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 Days | 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.

Warning:

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 adverse drug events, for technical assistance, or to obtain a copy of the Safety Data Sheet (SDS), please contact MED-PHARMEX at (800) 587-4306.

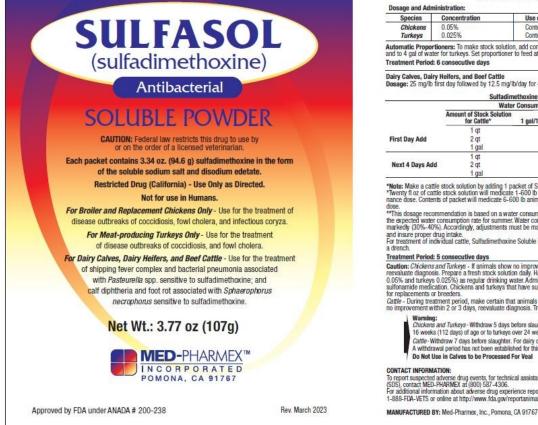
For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at http://www.fda.gov/reportanimalae

MANUFACTURED BY: Med-Pharmex, Inc., Pomona CA 91767

Rev. 06/2023

| | 54 | | | |
|--|----|--|--|--|
| | | | | |

Category



SOLUBLE POWDER

| Species | Concentration | Use of Directions |
|---------------------|---------------|---|
| Chickens Turkeys | 0.05% | Contents of packet to 50 gal of water Contents of packet to 100 gal of water |
| | | lution, add contents of 5 packets to 2 gal of water for chickens |

and to 4 gal of water for turkeys. Set proportioner to feed at a rate of 1 fl oz stock solution per gal of water Treatment Period: 6 consecutive days

I Doof C

| Daily Calves, Dail | y nenera, and beer bacue | |
|--------------------|---|--|
| Dosage: 25 mg/lb 1 | first day followed by 12.5 mg/lb/day for 4 days | |

Sulfadimethoxine in Wate

| | Water | Consumption | | | |
|-----------------|---|---|---|--|--|
| | Amount of Stock Solution for Cattle* | (Summer)* 1 gal/100 lb body weight** | (Winter)* 1 gal/150 lb body weight** | | |
| | 1 qt | 10 gal | 7 gal | | |
| First Day Add | 2 qt | 20 gal | 14 gal | | |
| | 1 gal | 40 gal | 28 gal | | |
| | 1 qt | 20 gal | 14 gal | | |
| Next 4 Days Add | 2 gt | 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 ib animal initialy of 2-600 ib animals on mainte-nance dose. Contents of packet will medicate 6-600 ib animals initialy of 2-600 ib animals on maintenance.

Indicates contains or particular of the state of the s 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: Chokes and Turkes - If animals show no improvement within 5 days, discontinue treatment and revealuate 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 sulfoamide medication. Chickens and turkeys that have survived fow icholera outbreaks should not be kept for replacements or breeders. *Catle -* 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.



Warning: 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 helfers 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:

CONTACT INFORMATION: To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact MED-PHAMMEX at (800) 587–4306. 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

Date

Date

| SULFASOL | sodium pov | der. for solution | | | | | | | |
|-------------------------------------|--------------|---------------------------------------|----------|---------|----------------------------|----------|------|--------------------|--|
| | Soularn por | | | | | | | | |
| Product Inform | nation | | | | | | | | |
| Product Type | | PRESCRIPTION ANIMAL DRUG Item Co | | | de (Sou | rce) | NDC: | C:54925-035 | |
| Route of Adminis | stration | ORAL | | | | | | | |
| | | | | | | | | | |
| Active Ingredie | ent/Active | Moiety | | | | | | | |
| | Ingre | edient Name | | | Basis o | of Stren | gth | Strength | |
| SULFADIMETHOXIN UNII:30CPC5LDEX) | IE SODIUM (U | INII: 49DG2B481W) (SULFADIMETHOXINE - | | | SULFADIMETHOXINE SODIUM | | | 94.6 g in 107 g | |
| | | | | | | | | | |
| Packaging | | | | | | | | | |
| # Item Code | Packa | ge Description | Marketin | g Start | Date | Marke | ting | End Date | |
| 1 NDC:54925-035-3 | 7 107 g in 1 | PACKET | | | | | | | |
| | | | | | | | | | |
| Marketing I | nformat | ion | | | | | | | |
| Marketing | Applica | tion Number or M | onograph | Mark | eting St | art | Mark | eting End | |

Citation

07/28/1998

Labeler - Med-Pharmex, Inc (025353699)

Revised: 6/2023

Med-Pharmex, Inc