

Date of Approval: JUL 28 1998

FREEDOM OF INFORMATION (FOI) SUMMARY

Sulfasol (sulfadimethoxine) Soluble Powder

ANADA 200-238

Med-Pharmex, Inc.

2727 Thompson Creek Road

Pomona, CA 91767-1861

*ANADA 200-238*

*FOIS 1*

## FREEDOM OF INFORMATION SUMMARY

### 1. General Information:

*ANADA Number:* 200-238

*Sponsor Name and Address:*

Med-Pharmex, Inc.  
2727 Thompson Creek Rd  
Pomona, CA 91767-1861

*Generic Name:* Sulfadimethoxine Soluble Powder

*Trade Name:* Sulfasol Soluble Powder

*Marketing Status:* OTC

*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.

Dosage Form(s), Route(s) of Administration and Recommended Dosages and Contraindications:

*Dosage Form:*

The product is available in the form of a soluble powder for oral administration.

*Route(s) of Administration and Recommended Dosages:*

The route of administration is as an oral solution administered to chickens at a concentration of 0.05% solution (Contents of packet diluted to 50 gallons of water) and to turkeys at a concentration of 0.025 % (contents of the packet diluted to 100 gallons of water). The treatment period is for 6 consecutive days. For Dairy Calves, Dairy Heifers and Beef Cattle the dosage is 25 mg/lb for the first day followed by 12.5 mg/lb/day for 4 days.

*Contraindications:* There are no known contraindications when used as directed.

## 2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA approval is based on a demonstration that the generic product is bioequivalent to the pioneer product.

Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer. If bioequivalence is demonstrated through a clinical end-point study, then a tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (Fifth GADPTRA Policy Letter: 55 FR 24645, June 18, 1990; Bioequivalence Guidance: 61 FR 26182 - 26186, May 24, 1996).

Based upon the formulation characteristics of the generic product, Med-Pharmex, Inc. was granted a waiver from conducting an *in vivo* bioequivalence study for Sulfasol Soluble Powder. The generic and pioneer products contain the same active and inactive ingredients and are oral solutions.

## 3. HUMAN FOOD SAFETY

### Tolerance

The tolerances established for the pioneer product apply to the generic product. Tolerances are established for residues of sulfadimethoxine in uncooked edible tissues of chickens, turkeys, and cattle as follows: 0.1 part per million (negligible residue). In milk at 0.01 part per million (negligible residue)(21 CFR 556.640).

### Withdrawal Time

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal time for sulfadimethoxine soluble powder is established under:

- |                                  |   |
|----------------------------------|---|
| 21 CFR 520.2220 a (e) (1) (iii)  | Broiler and Replacement Chickens- 5 days before slaughter.            |
| 21 CFR 520.2220 a (e) (2) (iii)  | Meat-Producing Turkeys- 5 days before slaughter                       |
| 21 CFR 520. 2220 a (e) (3) (iii) | Dairy Calves, Dairy Heifers and Beef Cattle- 7 days before slaughter. |

**Regulatory Methods for Residues:**

**Sulfadimethoxine:**

The regulatory analytical method for detection of residues of the drug is a thin layer densitometric procedure. This method is found in the Official Methods of Analysis of AOAC International, 16th edition.

**Human Safety Relative to Possession, Handling and Administration:**

Labeling contains adequate caution/warning statements.

**4. AGENCY CONCLUSION:**

This is an Abbreviated New Animal Drug Application (ANADA) filed under section 512(b)(2) of the Federal, Food, Drug and Cosmetic (FFD&C) Act.

Safety and effectiveness for this generic animal drug, Sulfadimethoxine Soluble Powder , were established by demonstration of chemical equivalence to the pioneer product, Pfizer's Albon® (NADA 046-285)

This generic product and the pioneer product have identical labeling indications for the gallon bottle for use in chickens, turkeys and cattle. The route and method of administration of the two drugs are identical. Both drugs are administered orally in the drinking water. The generic and pioneer products contain the same active and inactive ingredients. Therefore, in compliance with FDA policy implementing section 512(b)(2) of FFD&C Act, *in vivo* bioequivalency studies were neither necessary nor required.

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that Sulfasol (Sulfadimethoxine Soluble Powder), is safe and effective for its labeled indications when used under its proposed conditions of use.

Attachment: Generic and pioneer labeling

DRAFT-LABELINGFRONT PANEL3.77 oz (107 g) POUCH**SULFASOL**

(Brand of Sulfadimethoxine)

## ANTIBACTERIAL SOLUBLE POWDER

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 (107 g)

ANADA 200-238, Approved by FDA.

MED-PHARMEX, INC.  
Pomona, CA 91767

DRAFT-LABELING  
REAR PANEL-3.77 oz (107 g) POUCH

Dosage and Administration:

Species	Concentration	Use Directions
Chickens	0.05%	Contents of packet to 50 gal of water
Turkeys	0.025%	Contents of packet to 100 gal of water

**Automatic Proportioners** - 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 feed at rate of 1 fl oz stock solution per gal of water.

**Treatment Period: 6 consecutive days**

**Dairy Calves, Dairy Heifers, and Beef Cattle**

Dosage: 25 mg/lb first day followed by 12.5 mg/lb/day for 4 days.

**Sulfasal (sulfadimethoxine) in Water**

	Amount of Stock Solution for Cattle*	Water Consumption	
		(Summer)* 1 gal/100 lb body weight**	(Winter)* 1 gal/150 lb body weight**
First Day Add	1 qt	10 gal	7 gal
	2 qt	20 gal	14 gal
	1 gal	40 gal	28 gal
Next 4 Days Add	1 qt	20 gal	14 gal
	2 qt	40 gal	28 gal
	1 gal	80 gal	56 gal

\*Note: Make a cattle stock solution by adding 1 packet of Sulfasal 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, Sulfasal (sulfadimethoxine) Soluble Powder stock solution for cattle may be given as a drench. Administer using same mg/lb dosage as outlined above.

**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.**

Med-Pharmex, Inc.  
Pomona, CA 91767

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NOTE  
Pfizer  
CONTINUES TO  
USE THIS  
LABEL

**ALBON<sup>®</sup>**

(Brand of Sulfadimethoxine)

**ANTIBACTERIAL SOLUBLE POWDER**

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Net wt 3.77 oz (107 g)

NADA #046-285, Approved by FDA

**SB SmithKline Beecham**

**Dosage and Administration**

Species	Concentration	Use Directions
Chickens	0.05%	Contents of packet to 50 gal of water
Turkeys	0.025%	Contents of packet to 100 gal of water

**Automatic Proportioners**—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 feed at rate of 1 fl oz stock solution per gal of water.

**Treatment Period:** 6 consecutive days

**Dairy Calves, Dairy Heifers, and Beef Cattle**

**Dosage:** 25 mg/lb first day followed by 12.5 mg/lb/day for 4 days

**Albon (sulfadimethoxine) in Water**

	Amount of Stock Solution for Cattle*	Water Consumption	
		(Summer) 1 gal/100 lb body wt**	(Winter) 1 gal/150 lb body wt**
First Day Add	1 qt	10 gal	7 gal
	2 qt	20 gal	14 gal
	1 gal	40 gal	28 gal
Next 4 Days Add	1 qt	20 gal	14 gal
	2 qt	40 gal	28 gal
	1 gal	80 gal	56 gal

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

\*\*Twenty fl oz of cattle stock solution will medicate 1 600-lb animal initially or 12 600-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, 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, Albon (sulfadimethoxine) Soluble Powder stock solution for cattle may be given as a drench. Administer using same mg/lb dosage as outlined above.

**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**

Distributed by:  
SmithKline Beecham Animal Health  
West Chester, PA 19380, USA

942 0-8445