SMZ-MED 454- sodium sulfamethazine powder Bimeda, Inc.

SMZ-Med® 454 (sodium sulfamethazine) Soluble Powder Antibacterial For Animal Use Only Not for Human Use

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

Restricted Drug (California) - Use Only as Directed Approved by FDA under ANADA # 200-434

This 1 lb pouch contains 100% sodium sulfamethazine.

Convenient, once-a-day dosage in drinking water or as a drench

INDICATIONS:For the control and treatment of the following diseases when caused by one or more of the following pathogenic organisms susceptible to sulfamethazine.

For the Treatment of:

Cattle- Bacterial Pneumonia and Bovine Respiratory Disease Complex (Shipping Fever Complex) (*Pasteurella* spp.); Colibacillosis (Bacterial Scours) (*Escherichia coli*); Necrotic Pododermatitis (Foot Rot) (*Fusobacterium necrophorum*); Calf Diphtheria (*Fusobacterium necrophorum*); Acute Metritis (Streptococcus spp.)

Beef Cattle- Acute Mastitis (Streptococcus spp.)

Swine- Porcine Colibacillosis (Bacterial Scours) (*Escherichia coli*); Bacterial Pneumonia (*Pasteurella* spp.)

For the Control of:

Chickens - Infectious Coryza (*Avibacterium paragallinarum*); Coccidiosis (*Eimeria tenella, Eimeria necatrix*); Acute Fowl Cholera (*Pasteurella multocida*); Pullorum Disease (*Salmonella* Pullorum)

Turkeys- Coccidiosis (Eimeria meleagrimitis, Eimeria adenoeides)

RESIDUE WARNINGS: Do not medicate chickens or turkeys producing eggs for human consumption. To avoid drug residues in edible flesh withdraw medication from chickens and turkeys ten (10) days prior to slaughter for food.

Treated cattle must not be slaughtered for at least ten (10) days after the last dose. Exceeding five (5) consecutive days of treatment may cause violative tissue residue to remain beyond the withdrawal time. Do not use in calves under one (1) month of age or calves being fed an all-milk diet. Use in these classes of calves may cause violative residues to remain beyond the withdrawal time. Do not use in female dairy cattle 20 months of age or older. Use of sulfamethazine in this class of cattle may cause milk residues. Withdraw medication from swine fifteen (15) days prior to slaughter for food.

PRECAUTIONS: Have only medicated water available during treatment, and check carefully to ensure adequate drug dosage and water intake. Cattle and calves not drinking or eating must be dosed by drench or with immediate release sulfamethazine bolus. For best results, treat sick animals individually. For control of outbreaks of disease, medication should be initiated as soon as the diagnosis is determined.

Medicated cattle, swine, chickens and turkeys must actually consume enough medicated water which provides the recommended dosages. SMZ-Med 454 works fast. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. Excessive dosage may cause toxic reactions. Follow dosage and administration instructions carefully. Hatchability of eggs laid during medication of sulfas, and for short periods thereafter, may be adversely affected. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed a total of 5 consecutive days in cattle or swine.

The Safety Data Sheet (SDS) contains more detailed occupational safety information. To report adverse drug events, for technical assistance or to obtain a copy of the SDS, contact Bimeda, Inc. at 1-888-524-6332. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at www.fda.gov/reportanimalae.

Prepare Fresh Solutions Daily.

Administration in Drinking Water Prepare a 12.0% stock solution by adding the contents of this package to one gallon of water.

Dosage:

Cattle, Calves and Swine

1st day: 6 tablespoons (3 fl oz) for each 100 lb body weight, providing approximately 108 mg/lb (237.6 mg/kg) body weight.

2nd, 3rd, 4th days: 3 tablespoons (1 1/2 fl oz) for each 100 lb body weight, providing approximately 54 mg/lb (118.8 mg/kg) body weight.

Poultry: Add 2 tablespoons (1 fl oz) to each gallon, or one gallon of stock solution to 128 gallons. Following administration directions, this will provide a recommended dose of approximately 58 to 85 mg/lb/day (128 to 187 mg/kg/day) body weight in chickens and 50 to 124 mg/lb/day (110 to 273 mg/kg/day) body weight in turkeys, depending upon the dosage, age, class of chickens or turkeys, ambient temperature and other factors.

Administration:

Cattle, Calves, and Swine:

In Drinking Water: Add the required dose listed above to that amount of water that will be consumed in one day; consumption should be carefully checked. Factors such as temperature, humidity and disease will cause variable fluid intake. As a generalization, the animals listed above will consume approximately 1 gallon per 100 lb body weight per day.

As a Drench: Dilute the proper dose of stock solution, and drench or administer with dose syringe. Cattle and calves not drinking must be dosed by drench or with immediate release sulfamethazine bolus. For best results, pen-up animals to be treated, and treat sick animals individually.

Chickens and Turkeys: Add the required dose to that amount of water that will be consumed in one day. Water consumption should be carefully checked to ensure adequate drug intake. As a generalization, 100 turkeys will drink one gallon of water per day for each week of age; chickens will consume one-half this amount.

Infectious Coryza (in chickens): Medicate for 2 consecutive days.

Acute Fowl Cholera and Pullorum Disease (in chickens): Medicate for 6 consecutive days.

Coccidios is (in chickens and turkeys): Medicate as above for 2 days, then reduce drug concentration to one-half as above for 4 additional days.

Store at 20°C - 25°C (68°F - 77°F), with excursions permitted to 15°C - 30°C (59°F - 86°F).



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& Bimeda

SM2-Med* 454 is a Registered Toolsmark of Birneda, Inc.

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Product Information

PRESCRIPTION ANIMAL DRUG NDC:61133-8001 **Product Type** Item Code (Source)

Route of Administration ORAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength			
Sulfamethazine (UNII: 48U51W007F) (SULFAMETHAZINE - UNII:48U51W007F)	Sulfamethazine	453.5 g in 453.5 g			

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:61133-8001-3	453.5 g in 1 POUCH				
Marketing I	nformation				
Marketing	Application Number or M	onograph Marketing	Start Marketing End		
Category	Citation	Date	Date		
	Citation ANADA200434	Date 11/03/2006	Date		

Labeler - Bimeda, Inc. (060492923)

Registrant - Bimeda, Inc. (060492923)

Establishment						
Name	Address	ID/FEI	Business Operations			
Bimeda, Inc. Division of Cross Vetpharm Group Ltd.		060492923	manufacture			

Revised: 4/2024 Bimeda, Inc.