

ALBON- sulfadimethoxine suspension
Zoetis Inc.

ALBON[®] (sulfadimethoxine)

ALBON

(sulfadimethoxine)

Oral Suspension 5%

For the treatment of sulfadimethoxine-sensitive bacterial infections in dogs and cats and bacterial enteritis associated with coccidiosis in dogs.

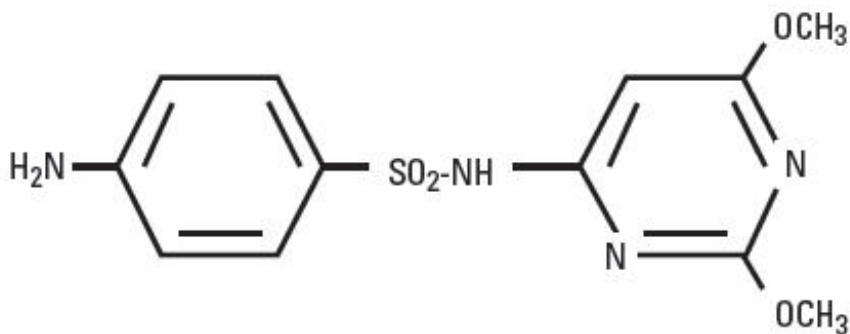
CAUTION

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

DESCRIPTION

Albon is a low-dosage, rapidly absorbed, long-acting sulfonamide, effective for the treatment of a wide range of bacterial infections commonly encountered in dogs and cats.

Sulfadimethoxine is a white, almost tasteless and odorless compound. Chemically, it is N¹-(2,6-dimethoxy-4-pyrimidinyl) sulfanilamide. The structural formula is:



CLINICAL PHARMACOLOGY

Sulfadimethoxine has been demonstrated clinically or in the laboratory to be effective against a variety of organisms, such as streptococci, klebsiella, proteus, shigella, staphylococci, escherichia, and salmonella.^{1,2} These organisms have been demonstrated in respiratory, genitourinary, enteric, and soft tissue infections of dogs and cats.

The systemic sulfonamides which include sulfadimethoxine are bacteriostatic agents. Sulfonamides competitively inhibit bacterial synthesis of folic acid (pteroylglutamic acid) from para-aminobenzoic acid. Mammalian cells are capable of utilizing folic acid in the presence of sulfonamides.

The tissue distribution of sulfadimethoxine, as with all sulfonamides, is a function of plasma levels, degree of plasma protein binding, and subsequent passive distribution in the tissues of the lipid-soluble un-ionized form. The relative amounts are determined by both its pKa and by the pH of each tissue. Therefore, levels tend to be higher in less acid tissue and body fluids or those diseased tissues having

high concentrations of leucocytes.²

In the dog, sulfadimethoxine is not acetylated as in most other animals, and it is excreted predominantly as the unchanged drug.³ Sulfadimethoxine has a relatively high solubility at the pH normally occurring in the kidney, precluding the possibility of precipitation and crystalluria. Slow renal excretion results from a high degree of tubular reabsorption,⁴ and plasma protein binding is very high, providing a blood reservoir of the drug. Thus, sulfadimethoxine maintains higher blood levels than most other long-acting sulfonamides. Single, comparatively low doses of Albon give rapid and sustained therapeutic blood levels.¹

To assure successful sulfonamide therapy (1) the drug must be given early in the course of the disease, and it must produce a high sulfonamide level in the body rapidly after administration, (2) therapeutically effective sulfonamide levels must be maintained in the body throughout the treatment period, (3) treatment should continue for a short period of time after the clinical signs have disappeared, and (4) the causative organisms must be sensitive to this class of drugs.

INDICATIONS AND USAGE

Albon is indicated for the treatment of respiratory, genitourinary tract, enteric, and soft tissue infections in dogs and cats:

-
- tonsillitis
 - pharyngitis
 - bronchitis
 - pneumonia
 - cystitis
 - nephritis
 - metritis
 - pyometra
 - pustular dermatitis
 - anal gland infections
 - abscesses
 - wound infections
 - bacterial enteritis
 - canine salmonellosis
 - bacterial enteritis associated with coccidiosis in dogs
-

when caused by streptococci, staphylococci, escherichia, salmonella, klebsiella, proteus or shigella organisms sensitive to sulfadimethoxine.

Limitations: Sulfadimethoxine is not effective in viral or rickettsial infections, and as with any antibacterial agent, occasional failures in therapy may occur due to resistant microorganisms. The usual precautions in sulfonamide therapy should be observed.

WARNING

Not for human use.

PRECAUTION

During treatment period, make certain that animals maintain adequate water intake.

If animals show no improvement within 2 or 3 days, reevaluate your diagnosis.

DOSAGE AND ADMINISTRATION:

Initial Dose: 25 mg/lb (55 mg/kg) of animal body weight.

Subsequent Daily Doses: 12.5 mg/lb (27.5 mg/kg) of animal body weight.

Dogs and cats should receive 1 teaspoonful of Albon Oral Suspension 5% per 10 lb of body weight (25 mg/lb or 55 mg/kg) as an initial dose, followed by 1/2 teaspoonful per 10 lb of body weight (12.5 mg/lb or 27.5 mg/kg) every 24 hours thereafter. Representative weights and doses are indicated in the following table:

Animal Weight	Initial Dose 25 mg/lb (55 mg/kg)	Subsequent Daily Doses 12.5 mg/lb (27.5 mg/kg)
5 lb (2.2 kg)	1/2 tsp (2 1/2 mL)	1/4 tsp (1 1/4 mL)
10 lb (4.5 kg)	1 tsp (5 mL)	1/2 tsp (2 1/2 mL)
20 lb (9.1 kg)	2 tsp (10 mL)	1 tsp (5 mL)
40 lb (18.2 kg)	4 tsp (20 mL)	2 tsp (10 mL)
80 lb (36.4 kg)	8 tsp (40 mL)	4 tsp (20 mL)

Treatment may be initiated with Albon Injection 40% to obtain effective blood levels almost immediately or to facilitate treatment of the fractious animal.

Length of treatment depends on the clinical response. In most cases treatment for 3–5 days is adequate. Treatment should be continued until the animal is asymptomatic for 48 hours.

TOXICITY AND SAFETY

Data regarding acute and chronic toxicities of sulfadimethoxine indicate the drug is very safe. The LD₅₀ in mice is greater than 2 g/kg of body weight when administered intraperitoneally and greater than 16 g/kg when administered orally. In dogs receiving massive single oral doses of 3.2 g/kg of body weight, diarrhea was the only adverse effect observed. Dogs given 160 mg/kg of body weight orally daily for 13 weeks showed no signs of toxicity.

STORAGE

Store at controlled room temperature 15°–30°C (59°–86°F).

HOW SUPPLIED

Albon Oral Suspension is available in 60- and 473-mL bottles; each tsp (5 mL) contains 250 mg sulfadimethoxine in a custard-flavored carrier.

REFERENCES

1. Data on file, Zoetis Inc.
2. Stowe CM: The sulfonamides. In Jones LM (ed), *Veterinary Pharmacology and Therapeutics*, Ames, Iowa, Iowa State University Press, chapter 33, 1965.
3. Bridges JW, Kirby MR, Walker SR, *et al*: Species differences in the metabolism of sulfadimethoxine. *Biochem J* 109:851, 1968.
4. Baggot JD: Some aspects of drug persistence in domestic animals. *Res Vet Sci* 11(2):130, 1970.

Approved by FDA under NADA # 043-785
Product of China

zoetis

Distributed by:
Zoetis Inc.
Kalamazoo, MI 49007

40026001
Revised: January 2019

PRINCIPAL DISPLAY PANEL - 60 mL Bottle Label

ALBON[®]
(sulfadimethoxine)
Oral Suspension 5%
For oral use in dogs and cats
For the treatment of sulfadimethoxine-sensitive bacterial infections in dogs and cats and bacterial enteritis associated with coccidiosis in dogs. does not meet USP for pH

250 mg/5 mL

60 mL
Approved by FDA under
NADA # 043-785

zoetis

LOT/EXP:
4 0 0 2 6 0 0 0

Dosage: To be administered in amounts to provide 25 mg/lb (55 mg/kg) for initial doses, followed by 12.5 mg/lb (27.5 mg/kg) for maintenance doses every 24 hours.

Animal Weight	Initial Dose	Subsequent Daily Doses
5 lb (2.2 kg)	2.5 mL (1/2 tsp)	1.25 mL (1/4 tsp)
10 lb (4.5 kg)	5 mL (1 tsp)	2.5 mL (1/2 tsp)
20 lb (9.1 kg)	10 mL (2 tsp)	5 mL (1 tsp)

For detailed dosage recommendations, indications, limitations, and precautions, see package insert.
During treatment period, make certain that animals maintain adequate water intake.
Shake Well Before Using
Store at Controlled Room Temperature 15°-30°C (59°-86°F)


zoetis
Distributed by:
Zoetis Inc.
Kalamazoo, MI 49007

Product of China

THE EYE
ORANGE LABEL
INDICATIONS

FP0:UPC
0 87219 01791 3

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label



zoetis
Distributed by:
Zoetis Inc.
Kalamazoo, MI 49007

THE ONE
ASSURANCE
DIFFERENCE

Product of China

ALBON[®]
(sulfadimethoxine)
Oral Suspension 5%

For oral use in dogs and cats

For the treatment of sulfadimethoxine-sensitive bacterial infections in dogs and cats and bacterial enteritis associated with coccidiosis in dogs.

does not meet USP for pH

Not for Human Use

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

250 mg/5 mL

473 mL

Approved by FDA under
NADA # 043-785

4 00025999
LOT/EXP

zoetis

Dosage: To be administered in amounts to provide 25 mg/lb (55 mg/kg) for initial dose, followed by 12.5 mg/lb (2.5 mg/kg) for maintenance doses every 24 hours.

Animal Weight	Initial Dose	Subsequent Daily Doses
5 lb (2.2 kg)	2.5 mL (1/2 tsp)	1.25 mL (1/4 tsp)
10 lb (4.5 kg)	5 mL (1 tsp)	2.5 mL (1/2 tsp)
20 lb (9.1 kg)	10 mL (2 tsp)	5 mL (1 tsp)

For detailed dosage recommendations, indications, limitations, and precautions, see package insert.

During treatment period, make certain that animals maintain adequate water intake. Shake Well Before Using

Store at Controlled Room Temperature 15°-30° C (59°-86° F)

ALBON

sulfadimethoxine suspension

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:54771-8435
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFADIMETHOXINE (UNII: 30CPC5LDEX) (SULFADIMETHOXINE - UNII:30CPC5LDEX)	SULFADIMETHOXINE	250 mg in 5 mL

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CUSTARD	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-8435-1	60 mL in 1 BOTTLE, GLASS		

2 | NDC:54771-8435-2 | 473 mL in 1 BOTTLE, GLASS

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA043785	07/02/1971	

Labeler - Zoetis Inc. (828851555)

Revised: 11/2019

Zoetis Inc.