

ALBON- sulfadimethoxine tablet
Zoetis Inc.

ALBON® Tablets

ALBON®
(sulfadimethoxine tablets)
Tablets

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

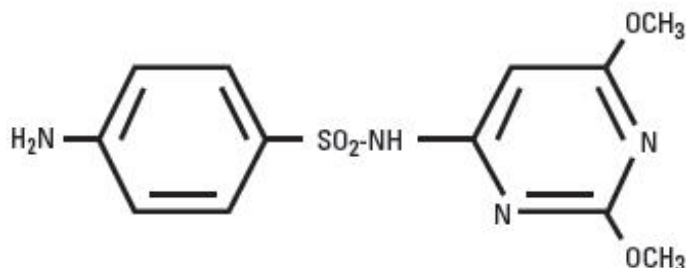
CAUTION

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:



Action

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 pK_a 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	pustular dermatitis
pharyngitis	anal gland infections
bronchitis	abscesses
pneumonia	wound infections
cystitis	bacterial enteritis
nephritis	canine salmonellosis
metritis	bacterial enteritis associated
pyometra	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.

For ease of administration in animals of varying weights, 3 tablet sizes are provided. The following table indicates how dosage may be adjusted depending on tablet size and body weight. Subsequent doses should be given at 24-hour intervals.

Tablet Size	Approximate Animal Weight	Initial Dose 25 mg/lb (55 mg/kg)	Subsequent Daily Doses 12.5 mg/lb (27.5 mg/kg)
125 mg	5 lb (2.2 kg)	1 tablet	1/2 tablet

250 mg	10 lb (4.5 kg)	1 tablet	1/2 tablet
500 mg	20 lb (9.1 kg)	1 tablet	1/2 tablet

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 Tablets are available in the following strengths for dogs and cats: 125 mg, 250 mg, or 500 mg sulfadimethoxine per tablet.

REFERENCES

1. Data on file, Pfizer Animal Health.
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 # 015-102

zoetis

Distributed by:

Zoetis Inc.

Kalamazoo, MI 49007

40028552

Revised: August 2019

PRINCIPAL DISPLAY PANEL - 125 mg Tablet Bottle Label

40028603

0 87219 01781 4

FP0 : UPC @ 80 %

ALBON[®]
(sulfadimethoxine tablets)

Not for Human Use

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

125 mg

200 Tablets

Approved by FDA under NADA # 015-102

zoetis

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

Recommended Dosage: Animals should receive 1 tablet for each 5 lb of body weight as an initial dose, and 1/2 tablet for each 5 lb of body weight daily for 3-5 days. For detailed instructions for use see package insert.

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

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

Distributed by:
Zoetis Inc.
Kalamazoo, MI 49007
Product of China

PRINCIPAL DISPLAY PANEL - 250 mg Tablet Bottle Label

40028613

0 87219 01783 8

FP0 : UPC

ALBON[®]
(sulfadimethoxine tablets)

Not for Human Use

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

250 mg

500 Tablets

Approved by FDA under NADA # 015-102

zoetis

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

Recommended Dosage: Animals should receive 1 tablet for each 10 lb of body weight as an initial dose, and 1/2 tablet for each 10 lb of body weight daily for 3-5 days.

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

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

Distributed by:
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PRINCIPAL DISPLAY PANEL - 500 mg Tablet Bottle Label



ALBON

sulfadimethoxine tablet

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:54771-8431
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFADIMETHOXINE (UNII: 30CPC5LDEX) (SULFADIMETHOXINE - UNII:30CPC5LDEX)	SULFADIMETHOXINE	125 mg

Product Characteristics

Color	WHITE	Score	2 pieces
Shape	ROUND (Bi-convex, cylindrical)	Size	8mm
Flavor		Imprint Code	ALBON;125
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-8431-1	200 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA015102	12/14/1964	

ALBON

sulfadimethoxine tablet

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:54771-8432
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Product Characteristics

Color	WHITE	Score	2 pieces
Shape	ROUND (Flat faced, cylindrical with beveled edges)	Size	10mm
Flavor		Imprint Code	ALBON;250
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-8432-1	500 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA015102	12/14/1964	

ALBON

sulfadimethoxine tablet

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:54771-8433
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFADIMETHOXINE (UNII: 30CPC5LDEX) (SULFADIMETHOXINE - UNII:30CPC5LDEX)	SULFADIMETHOXINE	500 mg

Product Characteristics

Color	WHITE	Score	4 pieces
Shape	ROUND (Flat faced, cylindrical with beveled edges)	Size	13mm
Flavor		Imprint Code	ALBON;500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-8433-1	100 in 1 BOTTLE, PLASTIC		
2	NDC:54771-8433-2	500 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA015102	12/14/1964	

Labeler - Zoetis Inc. (828851555)

Revised: 11/2019

Zoetis Inc.