PRIMOR- sulfadimethoxine and ormetoprim tablet Zoetis Inc.

PRIMOR[®] (sulfadimethoxine/ormetoprim) Tablets

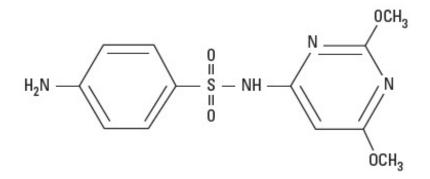
CAUTION

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

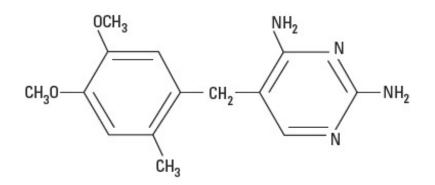
DESCRIPTION

Primor is an antimicrobial drug containing sulfadimethoxine and ormetoprim in a 5 to 1 ratio. The combination of these 2 compounds results in the potentiation of sulfadimethoxine, providing increased efficacy, a broadened spectrum of activity to include some sulfonamide-resistant organisms, and reduction in the rate of resistance development.

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



Ormetoprim is a white, almost tasteless powder. Chemically, it is 2,4-diamino-5-(4,5-dimethoxy-2-methylbenzyl)-pyrimidine. The structural formula is:



CLINICAL PHARMACOLOGY

Sulfadimethoxine is not acetylated in the dog, as in most other animals, and 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. 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 sulfadimethoxine give rapid and sustained therapeutic blood levels.⁴

The systemically active 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.

Ormetoprim, like other diaminopyrimidines, inhibits the reduction of dihydrofolic acid to tetrahydrofolic acid by bacterial cells.

Sulfadimethoxine/ormetoprim thus blocks 2 sequential steps of the folic acid metabolism of bacteria, depriving them of folate coenzymes. Potentiated sulfonamides have been shown to exhibit bactericidal as well as bacteriostatic action.

Microbiology

Sulfadimethoxine is a low-dosage, rapidly absorbed, long-acting sulfonamide effective for the treatment of a wide range of bacterial infections commonly encountered in dogs. Sulfadimethoxine has been demonstrated under laboratory and field conditions to be effective against a variety of gram-positive and gram-negative, aerobic and anaerobic organisms belonging to the genera *Streptococcus, Klebsiella, Proteus, Shigella, Staphylococcus, Escherichia, Salmonella,* and *Clostridium*.^{1,2} Most strains of these organisms were found to be susceptible to Primor *in vitro*, but the *in vivo* significance has not been determined for some canine isolates.

Ormetoprim potentiates the activity of sulfadimethoxine. The *in vitro* antibacterial spectrum and activity of the 2 compounds are very similar. On a molar basis, ormetoprim is more active than sulfadimethoxine. Sulfadimethoxine/ormetoprim shows enhanced *in vitro* and *in vivo* activity (potentiation) over that of either compound used alone. *In vitro*, this potentiation results in a reduction of the minimum inhibitory concentration of each drug, and an increase in activity against sulfonamide-resistant organisms, such as *Streptococcus, Staphylococcus, Corynebacterium, Escherichia, Klebsiella, Proteus, Brucella, Bordetella*, and *Clostridium*.¹ The susceptibility of organisms to Primor Tablets should be determined using a potentiated sulfonamide sensitivity disc such as sulfa-methoxazole and trimethoprim (BBL[®] Sensi-Disc[®] SXT¹). Specimens for susceptibility testing should be collected prior to initiation of therapy.

In an experimentally induced, controlled soft tissue infection study in dogs, the therapeutic efficacy of Primor was significantly greater than the 2 individual components when administered separately, providing clear evidence of the potentiation of sulfadimethoxine by ormetoprim in the target species.¹

¹ BBL[®] and Sensi-Disc[®] are registered trademarks owned by Becton, Dickinson and Company, Paramus, New Jersey.

Blood Levels

Blood Levels:¹ Therapeutically effective blood levels of both sulfadimethoxine and ormetoprim are obtained and maintained in dogs when using the recommended Primor dosing regimen of 25 mg/lb on day one and of 12.5 mg/lb on following days. Blood levels of sulfadimethoxine and ormetoprim were studied in 2 male and 2 female dogs. The initial drug dose was administered at zero hours. Blood samples were taken at 11 intervals, 6 of which are reported in Table 1. A second dose of Primor was administered at mediately following the 24-hour blood samples and blood values were determined 2 hours later (26 hours from the initial dose).

Table 1. Blood levels (mcg/mL) obtained with administration of a 25 mg/lb dose of Primor followed with a 12.5 mg/lb dose at 24 hours

Sample2 hr8 hr24 hr*26 hr32 hr48 hrSulfadimethoxine23.0041.0039.0060.0067.0036.00Ormetoprim1.040.550.091.080.440.03* Sample collected before administration of the second dose.

*Sample collected before administration of the second dose.

INDICATIONS AND USAGE

Primor is for the treatment of skin and soft tissue infections (wounds and abscesses) in dogs caused by strains of *Staphylococcus aureus* and *Escherichia coli* and urinary tract infections caused by *Escherichia coli, Staphylococcus* spp., and *Proteus mirabilis* susceptible to sulfadimethoxine/ormetoprim.

CONTRAINDICATIONS

Primor should not be used in dogs showing marked liver parenchymal damage, blood dyscrasias, or in those with a history of sulfonamide hypersensitivity.

WARNING

Not for human use. For use in dogs only. Keep out of reach of children.

PRECAUTIONS

Decreased water consumption and aciduria enhance the probability of the formation of sulfonamide crystals in the urine. Monitoring urine samples for crystal formation is recommended from animals with acid urine receiving the drug. As with any sulfonamide therapy, make certain dogs maintain adequate water intake. If dogs show no improvement within 2 or 3 days, reevaluate the diagnosis.

Safety in breeding dogs has not been established.

ADVERSE REACTIONS

Conditions reported following use of sulfonamides or potentiated sulfonamides include polyarthritis, urticaria, facial swelling, fever, hemolytic anemia, polydypsia, polyuria, hepatitis, vomiting, anorexia, diarrhea, and neurologic disorders. In rare instances, neurologic signs including behavioral changes, ataxia, seizures, aggression, and hyperexcitability have been reported. Keratitis sicca, possibly due to prolonged use of sulfonamides, has been reported.

Individual animal hypersensitivity may result in local or generalized reactions. Anaphylactoid reactions, although rare, may also occur.

Antidote: Epinephrine for anaphylactoid reactions.

CONTACT INFORMATION

For a copy of the Safety Data Sheet or to report adverse reactions, call Zoetis Inc. at 1-888-963-8471. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or www.fda.gov/reportanimalae.

DOSAGE AND ADMINISTRATION

Administer an initial oral dose of 25 mg/lb (55 mg/kg) of body weight on the first day of treatment. Administer subsequent daily doses at the rate of 12.5 mg/lb (27.5 mg/kg) of body weight. Continue treatment for at least 2 days after remission of clinical signs. Do not extend treatment for more than 21 consecutive days. Suggested dosage schedules follow:

	Body Weight Up To	(lb)No. of Tablets First Day	No. of Tablets Subsequent Days
Primor 120	5	1	1/2
	10	2	1
	15	3	1 1/2
Primor 240	10	1	1/2
	20	2	1
	30	3	1 1/2
Primor 600	25	1	1/2
	50	2	1
Primor 1200) 50	1	1/2
	100	2	1

For optimal therapeutic effect: (1) the drug must be given early in the course of the disease; (2) therapeutically effective levels must be maintained in the body throughout the treatment period; (3) treatment should continue for at least 2 days after remission of clinical signs; and (4) the causative bacterial agents must be sensitive to the drug.

TOXICITY AND SAFETY

TOXICITY AND SAFETY:¹ Toxicity data for Primor indicate that the drug is safe when used at the recommended dosage.

Following oral administration of Primor to dogs at 27.5 mg/kg/day (12.5 mg/lb/day) for 8 weeks, no changes were noted in hematology, blood chemistry, urinalysis, gross pathology, and histopathology, except for elevated serum cholesterol, increased thyroid and liver weights, enlarged basophilic cells in the pituitary, and mild follicular thyroid hyperplasia. These changes are known to be associated with prolonged administration of sulfonamides to dogs and have been shown to be reversible.

STORAGE

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

HOW SUPPLIED

Primor is available as scored tablets for the following potencies: 120 mg, 240 mg, 600 mg, and 1200 mg.

PRIMOR 120:	PRIMOR 600:
100 mg sulfadimethoxine/20 mg	500 mg sulfadimethoxine/100 mg
ormetoprim	ormetoprim
PRIMOR 240:	PRIMOR 1200:
200 mg sulfadimethoxine/40 mg	1000 mg sulfadimethoxine/200 mg
ormetoprim	ormetoprim

REFERENCES

1. Data on file, Zoetis Inc.

2. Bevill RF: Sulfonamides. Booth NM, MacDonald LE (eds), *Veterinary Pharmacology and Therapeutics*, 5th ed, The Iowa State University Press, Ames, Iowa, chapter 48, 1982.

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.

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Approved by FDA under NADA # 100-929

zoetis

Distributed by: Zoetis Inc. Kalamazoo, MI 49007

40034731

PRINCIPAL DISPLAY PANEL - 120 mg Tablet Bottle Label



PRINCIPAL DISPLAY PANEL - 240 mg Tablet Bottle Label

6 87219018	PRIMOR® 240 (sulfadimethoxine/ormetoprim) Each tablet contains 200 mg sulfadimethoxine and 40 mg ormetoprim. For use in dogs only Not for Human Use Keep Out of Reach of Children Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.	f skin and soft tissue infections asses) in dogs caused by strains aureus and Escherichia coli ons caused by <i>Escherichia coli</i> p., and <i>Proteus mirabilis</i> susceptible e/ormetoprim. certain that animals maintain ads. Safety in breeding animals has ads. Safety in breeding animals has ads. Safety in breeding animals has ads. For information on dosage, for Use: For information on dosage, adverse events, see package insert l Boom Temperature 15°–30°C TMETME CON DISCIPLING
801	<i>100 tablets</i> Approved by FDA under NADA # 100-929	treatment o treatment o hylococcus tractinfecti lococcus sp dimethoxin dimethoxin tie water int an establish mendations acology, and t Controlled SF) treat treat to 0,014 490 200, M1 490
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PRINCIPAL DISPLAY PANEL - 600 mg Tablet Bottle Label



PRINCIPAL DISPLAY PANEL - 1200 mg Tablet Bottle Label

0 87219 01809 5	<section-header><text><text><text><text><text><text><text><text><text></text></text></text></text></text></text></text></text></text></section-header>	For the treatment of skin and soft tissue infections (wounds and abscesses) in dogs caused by strains of <i>Staphylococcus aureus</i> and <i>Escherichia coli</i> and urinary tract infections caused by <i>Escherichia</i> <i>coli, Staphylococcus</i> spp., and <i>Proteus mirabilis</i> susceptible to sulfadimethoxine/ormetoprim.	Precaution: Make certain that animals maintain adequate water intake. Safety in breeding animals has not been established. Recommendations for Use: For information on dosage, pharmacology,	and adverse events, see package insert. Store at Controlled Room Temperature 15°–30°C (59°–86°F) onertwe
Zoetis Distributed by: Zoetis Inc. Kalamazoo, MI 49007 4 00 3 4 7 5 8	zoetis	For the treatment of abscesses) in dogs <i>Escherichia coli</i> and <i>coli, Staphylococcu</i> sulfadimethoxine/or	Precaution: Make Safety in breeding Recommendations	and adverse events, Store at Controlled F 15°-30°C (59°-86°F)

PRIMOR

sulfadimethoxine and ormetoprim tablet

Product Information Prescription ANIMAL DRUG Item Code (Source) NDC:54771-8440

Route of Administ	ration	ORAL						
Active Ingredie	nt/Activ	e Moiety						
	In	gredient N	lame			Basis of St	rength	Strength
sulfadimethoxine (U					C5LDEX)	sulfadimethox	ine	100 mg
ormetoprim (UNII: M3	EFS 94984) (ormetoprin	n - UNII:M3E	EFS 94984)		ormetoprim		20 mg
Product Charac	teristic	S						
Color	b	lue	Score			2 piece	S	
Shape	C	VAL	Size			10mm		
Flavor			Imprint (Code		Primor;	120	
Contains								
Packaging								
# Item Code	Pac	kage Desc	ription	Marketin	g Start Da	ate Mark	ceting E	nd Date
1 NDC:54771-8440-1	100 in	1 BOTTLE						
2 NDC:54771-8440-2	1000 ir	1 BOTTLE						
Marketing Ir	nforma	ation						
Marketing Category	Appli	cation Num Cit	ber or Moration	onograph		ing Start ate		ting End ate
NADA	NADA100	929			11/24/198	9		
PRIMOR								
ulfadimethoxine a	nd orme	toprim tabl	et					
Product Inform	ation							
		PRESCRIP		AL DRUG	ltem Code	(Source)	NDC:54	771-8441
Product Type						-		
Product Type Route of Administ	ration	ORAL						

Active Ingredient/Active Moiety							
Ingredient Name	Basis of Strength	Strength					
sulfadimethoxine (UNII: 30CPC5LDEX) (sulfadimethoxine - UNII:30CPC5LDEX)	sulfadimethoxine	200 mg					
ormetoprim (UNII: M3EFS94984) (ormetoprim - UNII:M3EFS94984)	ormetoprim	40 mg					

Product Characteristics

Color	blue	Score	2 pieces
Shape	OVAL	Size	13mm
Flavor		Imprint Code	Primor;240

Contains							
Packaging							
# Item Code	Packa	ge Description	Marketing	g Start Date	Mar	keting B	End Date
NDC:54771-8441-1	100 in 1 B	OTTLE					
2 NDC:54771-8441-2	500 in 1 B	OTTLE					
Marketing In	format	ion					
Marketing	Applicat	tion Number or M Citation	onograph	Marketing Date			eting End Date
Category NADA	NADA100929			11/24/1989		L	Jate
	11/12/110052	5		11,21,1505			
PRIMOR							
ulfadimethoxine an	nd ormetor	prim tablet					
Product Informa	ation						
		PRESCRIPTION ANIM		ltem Code (So		NDC:5/	4771-8442
Product Type			AL DRUG		Jurce)	NDC.5	+//1-0442
Route of Administr	ation	ORAL					
Activo Ingradian	t/Activo	Mojoty					
Active Ingredien		-		Pa	sic of St	ronath	Strongt
-	Ingr	edient Name	ne - LINII: 30CPC			-	-
sulfadimethoxine (UN	ingr III: 30CPC5L	edient Name DEX) (sulfadimethoxi		C5LDEX) sulfa	adimethox	-	500 mg
sulfadimethoxine (UN	ingr III: 30CPC5L	edient Name DEX) (sulfadimethoxi		C5LDEX) sulfa		-	-
sulfadimethoxine (UN	ingr III: 30CPC5L	edient Name DEX) (sulfadimethoxi		C5LDEX) sulfa	adimethox	-	500 mg
sulfadimethoxine (UN ormetoprim (UNII: M3E	ing r NII: 30CPC5L EFS94984) (d	edient Name DEX) (sulfadimethoxi		C5LDEX) sulfa	adimethox	-	500 mg
sulfadimethoxine (UN ormetoprim (UNII: M3E Product Charact	ing r NII: 30CPC5L EFS94984) (d	edient Name DEX) (sulfadimethoxin prmetoprim - UNII:M31		C5LDEX) sulfa	adimethox	kine	500 mg
sulfadimethoxine (UN ormetoprim (UNII: M3E Product Charact Color	Ingr 111: 30CPC5L 2FS94984) (d 2FS94984) (d	edient Name DEX) (sulfadimethoxin prmetoprim - UNII:M3I Score		C5LDEX) sulfa	adimetho> etoprim	kine	500 mg
sulfadimethoxine (UN prmetoprim (UNII: M3E Product Charact Color Shape	Ingr NII: 30CPC5L FS94984) (c eristics blue	edient Name DEX) (sulfadimethoxin prmetoprim - UNII:M3I Score	EFS 94984)	C5LDEX) sulfa	adimethox etoprim 2 piece	kine IS	500 mg
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sulfadimethoxine (UN ormetoprim (UNII: M3E Product Charact Color Shape Flavor	Ingr NII: 30CPC5L FS94984) (c eristics blue	edient Name DEX) (sulfadimethoxin prmetoprim - UNII:M3 Score L Size	EFS 94984)	C5LDEX) sulfa	etoprim 2 piece 18mm	kine IS	500 mg
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PR	IMOR							
	adimethoxine	and ormeto	prim tablet					
Pr	oduct Infor	mation						
Pro	oduct Type		PRESCRIPTION ANIM	AL DRUG	ltem Code	(Source)	NDC:54	1771-8444
Ro	ute of Admini	istration	ORAL					
Ac	tive Ingredi	ient/Active	Moiety					
		Ingr	edient Name			Basis of St	rength	Strength
sulf	fadimethoxine	(UNII: 30CPC5L	.DEX) (sulfadimethoxi	ne - UNII:30CPC	C5LDEX)	sulfadimethoxi	ne	1000 mg
orm	netoprim (UNII:	M3EFS94984) (ormetoprim - UNII:M3	EFS94984)		ormetoprim		200 mg
Pro	oduct Chara	acteristics						
Col	or	blue			Score		2 pieces	;
Sha	аре	OVAL (biconvex	with flat sides)		Size		22mm	
Fla	vor				Imprint Co	ode	Primor;	1200
Со	ntains							
Ра	ckaging							
#	Item Code	e Packa	ge Description	Marketing	g Start Da	ate Mark	eting E	nd Date
1 M	NDC:54771-8444	-1 100 in 1 E	BOTTLE					
M	arketing	Informat	ion					
	Marketing Category		tion Number or M Citation	onograph		ting Start ate		ting End
						410		
NAC	U I	NADA10092	9		11/24/198	9		

Labeler - Zoetis Inc. (828851555)

Revised: 8/2021

Zoetis Inc.