

SULFAMETHOXAZOLE AND TRIMETHOPRIM- sulfamethoxazole and trimethoprim tablet **Northwind Pharmaceuticals**

WARNINGS

FATALITIES ASSOCIATED WITH THE ADMINISTRATION OF SULFONAMIDES, ALTHOUGH RARE, HAVE OCCURRED DUE TO SEVERE REACTIONS, INCLUDING STEVENS-JOHNSON SYNDROME, TOXIC EPIDERMAL NECROLYSIS, FULMINANT HEPATIC NECROSIS, AGRANULOCYTOSIS, APLASTIC ANEMIA AND OTHER BLOOD DYSCRASIAS.

SULFONAMIDES, INCLUDING SULFONAMIDE-CONTAINING PRODUCTS SUCH AS SULFAMETHOXAZOLE/TRIMETHOPRIM, SHOULD BE DISCONTINUED AT THE FIRST APPEARANCE OF SKIN RASH OR ANY SIGN OF ADVERSE REACTION. In rare instances, a skin rash may be followed by a more severe reaction, such as Stevens-Johnson syndrome, toxic epidermal necrolysis, hepatic necrosis, and serious blood disorders (see PRECAUTIONS). Clinical signs, such as rash, sore throat, fever, arthralgia, pallor, purpura or jaundice may be early indications of serious reactions.

Cough, shortness of breath, and pulmonary infiltrates are hypersensitivity reactions of the respiratory tract that have been reported in association with sulfonamide treatment.

Thrombocytopenia

Sulfamethoxazole/Trimethoprim-induced thrombocytopenia may be an immune-mediated disorder. Severe cases of thrombocytopenia that are fatal or life threatening have been reported. Thrombocytopenia usually resolves within a week upon discontinuation of sulfamethoxazole and trimethoprim.

The sulfonamides should not be used for treatment of group alpha beta-hemolytic streptococcal infections. In an established infection, they will not eradicate the streptococcus and, therefore, will not prevent sequelae such as rheumatic fever.

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including sulfamethoxazole and trimethoprim, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

DESCRIPTION

Sulfamethoxazole and Trimethoprim is a synthetic antibacterial combination product available in 800 mg sulfamethoxazole and 160 mg trimethoprim Double Strength tablets and 400 mg sulfamethoxazole and 80 mg trimethoprim tablets for oral administration. Each Double Strength tablet contains 800 mg sulfamethoxazole and 160 mg trimethoprim plus magnesium stearate, pregelatinized starch and sodium starch glycolate. Each tablet contains 400 mg sulfamethoxazole and 80 mg trimethoprim plus magnesium stearate, pregelatinized starch, and sodium starch glycolate. Trimethoprim is 2, 4-diamino-5-

(3,4,5 trimethoxybenzyl) pyrimidine: the molecular formula is C₁₄H₁₈N₄O₃. It is a white to light yellow, odorless, bitter compound with a molecular weight of 290.3.

Sulfamethoxazole is N1-(5-methyl-3-isoxazolyl) sulfanilamide; the molecular formula is C₁₀H₁₁N₃O₃S. It is almost white, odorless, tasteless compound with a molecular weight of 253.28

INDICATIONS & USAGE

To reduce the development of drug-resistant bacteria and maintain the effectiveness of sulfamethoxazole and trimethoprim tablets and other antibacterial drugs, sulfamethoxazole and trimethoprim tablets should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Urinary Tract Infections

For the treatment of urinary tract infections due to susceptible strains of the following organisms: *Escherichia coli*, *Klebsiella* species, *Enterobacter* species, *Morganella morganii*, *Proteus mirabilis* and *Proteus vulgaris*. It is recommended that initial episodes of uncomplicated urinary tract infections be treated with a single effective antibacterial agent rather than the combination.

Acute Otitis Media

For the treatment of acute otitis media in pediatric patients due to susceptible strains of *Streptococcus pneumoniae* or *Haemophilus influenzae* when in the judgment of the physician sulfamethoxazole and trimethoprim offers some advantage over the use of other antimicrobial agents. To date, there are limited data on the safety of repeated use of sulfamethoxazole and trimethoprim in pediatric patients under two years of age. Sulfamethoxazole and trimethoprim is not indicated for prophylactic or prolonged administration in otitis media at any age.

Acute Exacerbations of Chronic Bronchitis in Adults

For the treatment of acute exacerbations of chronic bronchitis due to susceptible strains of *Streptococcus pneumoniae* or *Haemophilus influenzae* when in the judgment of the physician sulfamethoxazole and trimethoprim offers some advantage over the use of a single antimicrobial agent.

Shigellosis

For the treatment of enteritis caused by susceptible strains of *Shigella flexneri* and *Shigella sonnei* when antibacterial therapy is indicated.

Pneumocystis Carinii Pneumonia

For the treatment of documented *Pneumocystis carinii* pneumonia and for prophylaxis against *Pneumocystis carinii* pneumonia in individuals who are immunosuppressed and considered to be at an increased risk of developing *Pneumocystis carinii* pneumonia.

Traveler's Diarrhea in Adults

For the treatment of traveler's diarrhea due to susceptible strains of enterotoxigenic *E. coli*.

CONTRAINDICATIONS

Sulfamethoxazole and trimethoprim is contraindicated in patients with a known hypersensitivity to trimethoprim or sulfonamides and in patients with documented megaloblastic anemia due to folate deficiency. Sulfamethoxazole and trimethoprim is also contraindicated in pregnant patients and nursing mothers, because sulfonamides pass the placenta and are excreted in the milk and may cause kernicterus. Sulfamethoxazole and trimethoprim is contraindicated in pediatric patients less than 2 months of age.

Sulfamethoxazole and trimethoprim is also contraindicated in patients with marked hepatic damage or with severe renal insufficiency when renal function status cannot be monitored.

PRECAUTIONS

General

Prescribing sulfamethoxazole and trimethoprim tablets in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria. Sulfamethoxazole and trimethoprim should be given with caution to patients with impaired renal or hepatic function, to those with possible folate deficiency (e.g., the elderly, chronic alcoholics, patients receiving anticonvulsant therapy, patients with malabsorption syndrome, and patients in malnutrition states) and to those with severe allergies or bronchial asthma. In glucose-6-phosphate dehydrogenase deficient individuals, hemolysis may occur. This reaction is frequently dose-related. (see CLINICAL PHARMACOLOGY and DOSAGE AND ADMINISTRATION).

Cases of hypoglycemia in non-diabetic patients treated with sulfamethoxazole and trimethoprim are seen rarely, usually occurring after a few days of therapy. Patients with renal dysfunction, liver disease, malnutrition or those receiving high doses of sulfamethoxazole and trimethoprim are particularly at risk.

Hematological changes indicative of folic acid deficiency may occur in elderly patients or in patients with preexisting folic acid deficiency or kidney failure. These effects are reversible by folic acid therapy.

Trimethoprim has been noted to impair phenylalanine metabolism but this is of no significance in phenylketonuric patients on appropriate dietary restriction.

As with all drugs containing sulfonamides, caution is advisable in patients with porphyria or thyroid dysfunction.

Use in the Treatment of and Prophylaxis for Pneumocystis Carinii Pneumonia in Patients with Acquired Immunodeficiency Syndrome (AIDS)

AIDS patients may not tolerate or respond to sulfamethoxazole and trimethoprim in the same manner as non-AIDS patients. The incidence of side effects, particularly rash, fever, leukopenia and elevated aminotransferase (transaminase) values, with sulfamethoxazole and trimethoprim therapy in AIDS patients who are being treated for Pneumocystis carinii pneumonia has been reported to be greatly increased compared with the incidence normally associated with the use of sulfamethoxazole and trimethoprim in non-AIDS patients. The incidence of hyperkalemia appears to be increased in AIDS patients receiving sulfamethoxazole and trimethoprim. Adverse effects are generally less severe in patients receiving sulfamethoxazole and trimethoprim for prophylaxis. A history of mild intolerance to sulfamethoxazole and trimethoprim in AIDS patients does not appear to predict intolerance of subsequent secondary prophylaxis.⁶ However, if a patient develops skin rash or any sign of adverse reaction, therapy with sulfamethoxazole and trimethoprim should be reevaluated (see WARNINGS).

High dosage of trimethoprim, as used in patients with Pneumocystis carinii pneumonia, induces a progressive but reversible increase of serum potassium concentrations in a substantial number of patients. Even treatment with recommended doses may cause hyperkalemia when trimethoprim is administered to patients with underlying disorders of potassium metabolism, with renal insufficiency, or if drugs known to induce hyperkalemia are given concomitantly. Close monitoring of serum potassium is warranted in these patients.

During treatment, adequate fluid intake and urinary output should be ensured to prevent crystalluria. Patients who are "slow acetylators" may be more prone to idiosyncratic reactions to sulfonamides.

Information for Patients

Patients should be counseled that antibacterial drugs including sulfamethoxazole and trimethoprim

tablets should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold).

When sulfamethoxazole and trimethoprim tablets are prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by sulfamethoxazole and trimethoprim tablets or other antibacterial drugs in the future.

Patients should be instructed to maintain an adequate fluid intake in order to prevent crystalluria and stone formation.

Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibiotic. If this occurs, patients should contact their physician as soon as possible.

Laboratory Tests

Complete blood counts should be done frequently in patients receiving sulfamethoxazole and trimethoprim; if a significant reduction in the count of any formed blood element is noted, sulfamethoxazole and trimethoprim should be discontinued. Urinalyses with careful microscopic examination and renal function tests should be performed during therapy, particularly for those patients with impaired renal function.

Drug Interactions

In elderly patients concurrently receiving certain diuretics, primarily thiazides, an increased incidence of thrombocytopenia with purpura has been reported.

It has been reported that sulfamethoxazole and trimethoprim may prolong the prothrombin time in patients who are receiving the anticoagulant warfarin. This interaction should be kept in mind when sulfamethoxazole and trimethoprim is given to patients already on anticoagulant therapy, and the coagulation time should be reassessed.

Sulfamethoxazole and trimethoprim may inhibit the hepatic metabolism of phenytoin. Sulfamethoxazole and trimethoprim, given at a common clinical dosage, increased the phenytoin half-life by 39% and decreased the phenytoin metabolic clearance rate by 27%. When administering these drugs concurrently, one should be alert for possible excessive phenytoin effect.

Sulfonamides can also displace methotrexate from plasma protein binding sites and can compete with the renal transport of methotrexate, thus increasing free methotrexate concentrations. There have been reports of marked but reversible nephrotoxicity with coadministration of sulfamethoxazole and trimethoprim and cyclosporine in renal transplant recipients.

Increased digoxin blood levels can occur with concomitant sulfamethoxazole and trimethoprim therapy, especially in elderly patients. Serum digoxin levels should be monitored.

Increased sulfamethoxazole blood levels may occur in patients who are receiving indomethacin. Occasional reports suggest that patients receiving pyrimethamine as malaria prophylaxis in doses exceeding 25 mg weekly may develop megaloblastic anemia if sulfamethoxazole and trimethoprim is prescribed.

The efficacy of tricyclic antidepressants can decrease when coadministered with sulfamethoxazole and trimethoprim. Like other sulfonamide-containing drugs, sulfamethoxazole and trimethoprim potentiates the effect of oral hypoglycemics. In the literature, a single case of toxic delirium has been reported

after concomitant intake of trimethoprim/sulfamethoxazole and amantadine.

In the literature, three cases of hyperkalemia in elderly patients have been reported after concomitant intake of trimethoprim/sulfamethoxazole and an angiotensin converting enzyme inhibitor.^{7,8}

Drug/Laboratory Test Interactions

Sulfamethoxazole and trimethoprim, specifically the trimethoprim component, can interfere with a serum methotrexate assay as determined by the competitive binding protein technique (CBPA) when a bacterial dihydrofolate reductase is used as the binding protein. No interference occurs, however, if methotrexate is measured by a radioimmunoassay (RIA).

The presence of sulfamethoxazole and trimethoprim may also interfere with the Jaffé alkaline picrate reaction assay for creatinine, resulting in overestimations of about 10% in the range of normal values.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis: Long-term studies in animals to evaluate carcinogenic potential have not been conducted with sulfamethoxazole and trimethoprim.

Mutagenesis: Bacterial mutagenic studies have not been performed with sulfamethoxazole and trimethoprim in combination. Trimethoprim was demonstrated to be nonmutagenic in the Ames assay. No chromosomal damage was observed in human leukocytes in vitro with sulfamethoxazole and trimethoprim alone or in combination; the concentrations used exceeded blood levels of these compounds following therapy with sulfamethoxazole and trimethoprim. Observations of leukocytes obtained from patients treated with sulfamethoxazole and trimethoprim revealed no chromosomal abnormalities.

Impairment of Fertility: No adverse effects on fertility or general reproductive performance were observed in rats given oral dosages as high as 350 mg/kg/day sulfamethoxazole plus 70 mg/kg/day trimethoprim.

Pregnancy

Teratogenic Effects: Pregnancy Category C

In rats, oral doses of 533 mg/kg or 200 mg/kg produced teratologic effects manifested mainly as cleft palates.

The highest dose which did not cause cleft palates in rats was 512 mg/kg or 192 mg/kg trimethoprim when administered separately. In two studies in rats, no teratology was observed when 512 mg/kg of sulfamethoxazole was used in combination with 128 mg/kg of trimethoprim. In one study, however, cleft palates were observed in one litter out of 9 when 355 mg/kg of sulfamethoxazole was used in combination with 88 mg/kg of trimethoprim.

In some rabbit studies, an overall increase in fetal loss (dead and resorbed and malformed conceptuses) was associated with doses of trimethoprim 6 times the human therapeutic dose. While there are no large, well-controlled studies on the use of sulfamethoxazole and trimethoprim in pregnant women, Brumfitt and Pursell,¹⁰ in a retrospective study, reported the outcome of 186 pregnancies during which the mother received either placebo or sulfamethoxazole and trimethoprim. The incidence of congenital abnormalities was 4.5% (3 of 66) in those who received placebo and 3.3% (4 of 120) in those receiving sulfamethoxazole and trimethoprim. There were no abnormalities in the 10 children whose mothers received the drug during the first trimester. In a separate survey, Brumfitt and Pursell also found no congenital abnormalities in 35 children whose mothers had received oral sulfamethoxazole and trimethoprim at the time of conception or shortly thereafter.

Because sulfamethoxazole and trimethoprim may interfere with folic acid metabolism, sulfamethoxazole and trimethoprim should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects: See CONTRAINDICATIONS section.

Nursing Mothers

See CONTRAINDICATIONS section.

Pediatric Use

Sulfamethoxazole and trimethoprim is not recommended for infants younger than 2 months of age (see INDICATIONS and CONTRAINDICATIONS sections).

Geriatric Use

Clinical studies of sulfamethoxazole and trimethoprim did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

There may be an increased risk of severe adverse reactions in elderly patients, particularly when complicating conditions exist, e.g., impaired kidney and/or liver function, possible folate deficiency, or concomitant use of other drugs. Severe skin reactions, generalized bone marrow suppression (see WARNINGS and ADVERSE REACTIONS sections), a specific decrease in platelets (with or without purpura), and hyperkalemia are the most frequently reported severe adverse reactions in elderly patients. In those concurrently receiving certain diuretics, primarily thiazides, an increased incidence of thrombocytopenia with purpura has been reported. Increased digoxin blood levels can occur with concomitant sulfamethoxazole and trimethoprim therapy, especially in elderly patients. Serum digoxin levels should be monitored. Hematological changes indicative of folic acid deficiency may occur in elderly patients. These effects are reversible by folinic acid therapy. Appropriate dosage adjustments should be made for patients with impaired kidney function and duration of use should be as short as possible to minimize risks of undesired reactions (see DOSAGE AND ADMINISTRATION section). The trimethoprim component of sulfamethoxazole and trimethoprim may cause hyperkalemia when administered to patients with underlying disorders of potassium metabolism, with renal insufficiency, or when given concomitantly with drugs known to induce hyperkalemia, such as angiotensin converting enzyme inhibitors. Close monitoring of serum potassium is warranted in these patients. Discontinuation of sulfamethoxazole and trimethoprim treatment is recommended to help lower potassium serum levels. Sulfamethoxazole and Trimethoprim tablets contain 0.515 mg (0.023 mEq) of sodium per tablet. Sulfamethoxazole and trimethoprim Double Strength Tablets contain 1.03 mg (0.046 mEq) of sodium per tablet.

Pharmacokinetics parameters for sulfamethoxazole were similar for geriatric subjects and younger adult subjects. The mean maximum serum trimethoprim concentration was higher and mean renal clearance of trimethoprim was lower in geriatric subjects compared with younger subjects (see CLINICAL PHARMACOLOGY: Geriatric Pharmacokinetics).

ADVERSE REACTIONS

The most common adverse effects are gastrointestinal disturbances (nausea, vomiting, anorexia) and allergic skin reactions (such as rash and urticaria). FATALITIES ASSOCIATED WITH THE ADMINISTRATION OF SULFONAMIDES, ALTHOUGH RARE, HAVE OCCURRED DUE TO SEVERE REACTIONS, INCLUDING STEVENS-JOHNSON SYNDROME, TOXIC EPIDERMAL NECROLYSIS, FULMINANT HEPATIC NECROSIS, AGRANULOCYTOSIS, APLASTIC ANEMIA AND OTHER BLOOD DYSCRASIAS (SEE WARNINGS SECTION).

Hematologic: Agranulocytosis, aplastic anemia, thrombocytopenia, leukopenia, neutropenia, hemolytic anemia, megaloblastic anemia, hypoprothrombinemia, methemoglobinemia, eosinophilia.

Allergic Reactions: Stevens-Johnson syndrome, toxic epidermal necrolysis, anaphylaxis, allergic myocarditis, erythema multiforme, exfoliative dermatitis, angioedema, drug fever, chills, Henoch-Schoenlein purpura, serum sickness-like syndrome, generalized allergic reactions, generalized skin eruptions, photosensitivity, conjunctival and scleral injection, pruritus, urticaria and rash. In addition, periarteritis nodosa and systemic lupus erythematosus have been reported.

Gastrointestinal: Hepatitis (including cholestatic jaundice and hepatic necrosis), elevation of serum

transaminase and bilirubin, pseudomembranous enterocolitis, pancreatitis, stomatitis, glossitis, nausea, emesis, abdominal pain, diarrhea, anorexia.

Genitourinary: Renal failure, interstitial nephritis, BUN and serum creatinine elevation, toxic nephrosis with oliguria and anuria, crystalluria and nephrotoxicity in association with cyclosporine.

Metabolic and Nutritional: Hyperkalemia (see PRECAUTIONS: Use in the Treatment of and Prophylaxis for Pneumocystis Carinii Pneumonia in Patients with Acquired Immunodeficiency Syndrome (AIDS)).

Neurologic: Aseptic meningitis, convulsions, peripheral neuritis, ataxia, vertigo, tinnitus, headache.

Psychiatric: Hallucinations, depression, apathy, nervousness.

Endocrine: The sulfonamides bear certain chemical similarities to some goitrogens, diuretics (acetazolamide and the thiazides) and oral hypoglycemic agents. Cross-sensitivity may exist with these agents. Diuresis and hypoglycemia have occurred rarely in patients receiving sulfonamides.

Musculoskeletal: Arthralgia and myalgia. Isolated cases of rhabdomyolysis have been reported with sulfamethoxazole and trimethoprim, mainly in AIDS patients.

Respiratory: Cough, shortness of breath and pulmonary infiltrates (see WARNINGS).

Miscellaneous: Weakness, fatigue, insomnia.

OVERDOSAGE

Acute

The amount of a single dose of sulfamethoxazole and trimethoprim that is either associated with symptoms of overdose or is likely to be life-threatening has not been reported. Signs and symptoms of overdose reported with sulfonamides include anorexia, colic, nausea, vomiting, dizziness, headache, drowsiness and unconsciousness. Pyrexia, hematuria and crystalluria may be noted. Blood dyscrasias and jaundice are potential late manifestations of overdose.

Signs of acute overdose with trimethoprim include nausea, vomiting, dizziness, headache, mental depression, confusion and bone marrow depression.

General principles of treatment include the institution of gastric lavage or emesis, forcing oral fluids, and the administration of intravenous fluids if urine output is low and renal function is normal. Acidification of the urine will increase renal elimination of trimethoprim. The patient should be monitored with blood counts and appropriate blood chemistries, including electrolytes. If a significant blood dyscrasia or jaundice occurs, specific therapy should be instituted for these complications. Peritoneal dialysis is not effective and hemodialysis is only moderately effective in eliminating sulfamethoxazole and trimethoprim.

Chronic

Use of sulfamethoxazole and trimethoprim at high doses and/or for extended periods of time may cause bone marrow depression manifested as thrombocytopenia, leukopenia and/or megaloblastic anemia. If signs of bone marrow depression occur, the patient should be given leucovorin 5 to 15 mg daily until normal hematopoiesis is restored.

NDC: 51655-111-20

MFG: 61971-120-05

SMZ/TMP

800/160MG

20 Tablets

Rx only

Lot#:

Exp. Date:

Each tablet contains: Sulfamethoxazole....800 mg Trimethoprim...160mg

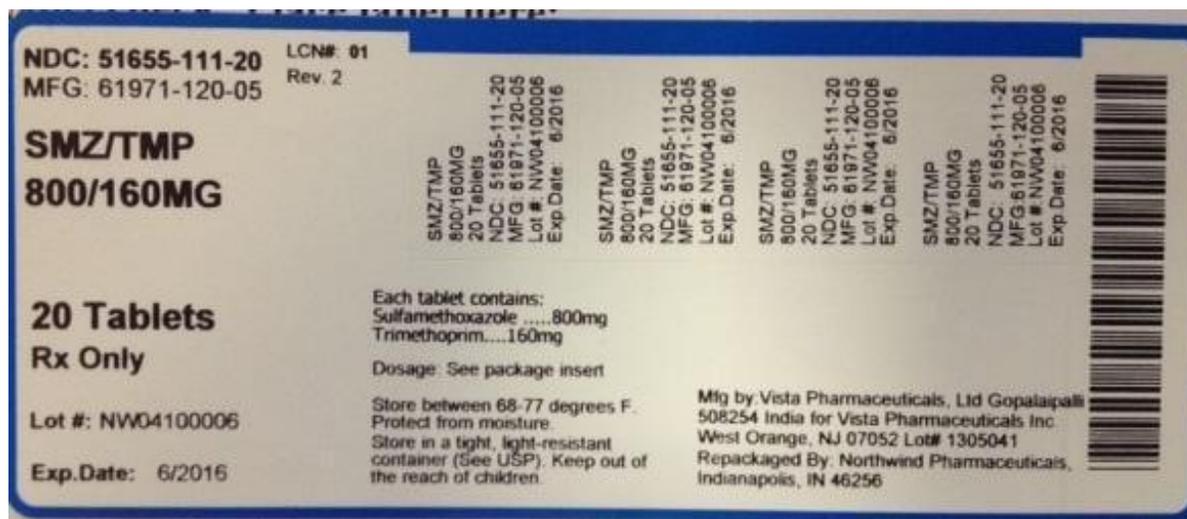
Dosage: See package insert

Store between 68-77 degrees F.

Protect from moisture. Store in a tight, light-resistant container (See USP). Keep out of the reach of children.

Mfg by: Vista Pharmaceuticals, Ltd Gopalaipalli 50824 India for Vista Pharmaceuticals Inc. West Orage, NJ 07052 Lot #

Repackaged by: Northwind Pharmaceuticals, Indianapolis, IN 46256



NDC: 51655-111-84

MFG: 61971-120-05

SMZ/TMP

800/160MG

14 Tablets

Rx only

Lot#:

Exp. Date:

Each tablet contains: Sulfamethoxazole....800 mg Trimethoprim...160mg

Dosage: See package insert

Store between 68-77 degrees F.

Protect from moisture. Store in a tight, light-resistant container (See USP). Keep out of the reach of children.

Mfg by: Vista Pharmaceuticals, Ltd Gopalaipalli 50824 India for Vista Pharmaceuticals Inc. West Orage, NJ 07052 Lot #

Repackaged by: Northwind Pharmaceuticals, Indianapolis, IN 46256

NDC: 51655-111-84
MFG: 61971-120-05

LCN#: 81
 Rev. 2

**Sulfamethoxazole
 & Trimethoprim
 800/160MG**

14 Tablets
Rx Only

Lot #: NW04100013
 Exp.Date: 5/2018

Sulfamethoxazole
 & Trimethoprim
 800/160MG
 14 Tablets
 NDC: 51655-111-84
 MFG: 61971-120-05
 Lot #: NW04100013
 Exp.Date: 5/2018

Sulfamethoxazole
 & Trimethoprim
 800/160MG
 14 Tablets
 NDC: 51655-111-84
 MFG: 61971-120-05
 Lot #: NW04100013
 Exp.Date: 5/2018

Each tablet contains:
 Sulfamethoxazole800mg
 Trimethoprim.....160mg

Dosage: See prescriber's
 instructions

Store between 68-77 degrees F.
 Protect from moisture.

Keep out of the reach of children.

Medication guide is found at
www.fda.gov/drugs/drugsafety/ucm085729

Mfg by Vista Pharmaceuticals, Ltd
 Gopalaipalli-508254, India
 Distributed by: Vista Pharmaceuticals, Inc.
 West Orange, NJ 07052 Lot# 1406012

Repackaged By: Northwind Pharmaceuticals,
 Indianapolis, IN 46256

NDC: 51655-111-87

MFG: 61971-120-05

SMZ/TMP

800/160MG

6 Tablets

Rx only

Lot#:

Exp. Date:

Each tablet contains: Sulfamethoxazole....800 mg Trimethoprim....160mg

Dosage: See package insert

Store between 68-77 degrees F.

Protect from moisture. Store in a tight, light-resistant container (See USP). Keep out of the reach of children.

Mfg by: Vista Pharmaceuticals, Ltd Gopalaipalli 50824 India for Vista Pharmaceuticals Inc. West Orage, NJ 07052 Lot #

Repackaged by: Northwind Pharmaceuticals, Indianapolis, IN 46256

NDC: 51655-111-87
MFG: 61971-120-05

LCN#: 82
 Rev. 2

**Sulfamethoxazole
 & Trimethoprim
 800/160MG**

6 Tablets
Rx Only

Lot #: NW04100011
 Exp.Date: 7/2016

Sulfamethoxazole
 & Trimethoprim
 800/160MG
 6 Tablets
 NDC: 51655-111-87
 MFG: 61971-120-05
 Lot #: NW04100011
 Exp.Date: 7/2016

Sulfamethoxazole
 & Trimethoprim
 800/160MG
 6 Tablets
 NDC: 51655-111-87
 MFG: 61971-120-05
 Lot #: NW04100011
 Exp.Date: 7/2016

Each tablet contains:
 Sulfamethoxazole800mg
 Trimethoprim.....160mg

Dosage: See prescribing directions

Store between 68-77 degrees F.
 Protect from moisture.

Store in a tight, light-resistant
 container. Keep this out of the
 reach of children.

Mfg by: Vista Pharmaceuticals, Ltd
 Gopalaipalli 508254 India for Vista
 Pharmaceuticals Inc. West Orange,
 NJ 07052 Lot# 1308058

Repackaged By: Northwind Pharmaceuticals,
 Indianapolis, IN 46256

NDC: 51655-111-829

MFG: 61971-120-05

SMZ/TMP

800/160MG

28 Tablets

Rx only

Lot#:

Exp. Date:

Each tablet contains: Sulfamethoxazole....800 mg Trimethoprim....160mg

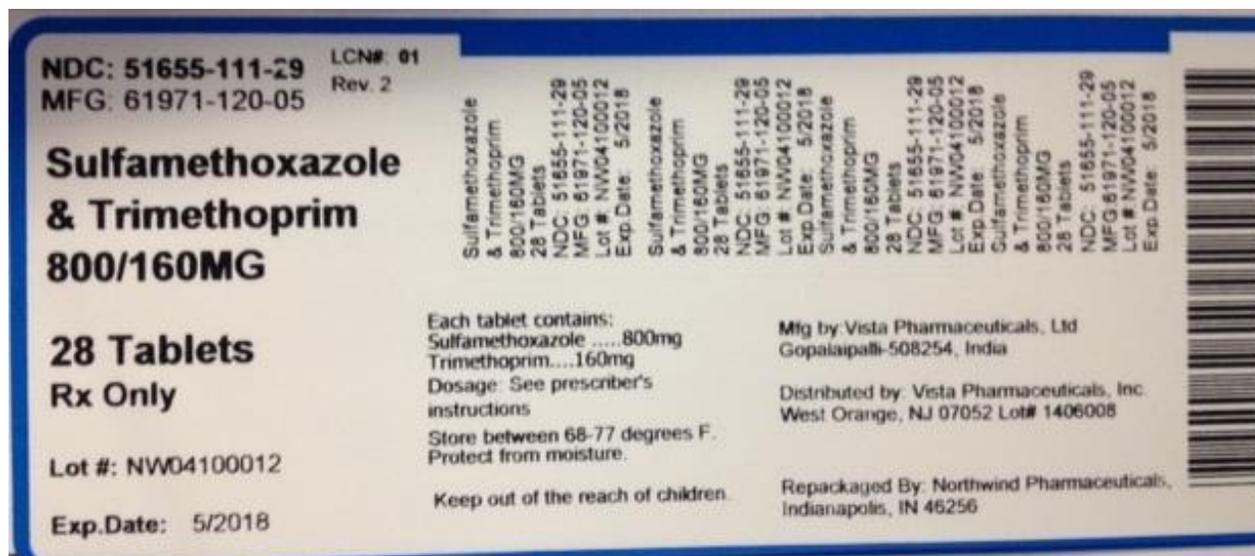
Dosage: See package insert

Store between 68-77 degrees F.

Protect from moisture. Store in a tight, light-resistant container (See USP). Keep out of the reach of children.

Mfg by: Vista Pharmaceuticals, Ltd Gopalaipalli 50824 India for Vista Pharmaceuticals Inc. West Orage, NJ 07052 Lot #

Repackaged by: Northwind Pharmaceuticals, Indianapolis, IN 46256



SULFAMETHOXAZOLE AND TRIMETHOPRIM

sulfamethoxazole and trimethoprim tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:51655-111(NDC:61971-120)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFAMETHOXAZOLE (UNII: JE42381TNV) (SULFAMETHOXAZOLE - UNII:JE42381TNV)	SULFAMETHOXAZOLE	800 mg
TRIMETHOPRIM (UNII: AN164J8Y0X) (TRIMETHOPRIM - UNII:AN164J8Y0X)	TRIMETHOPRIM	160 mg

Product Characteristics

Color	white	Score	2 pieces
Shape	OVAL	Size	19mm
Flavor		Imprint Code	VP120
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51655-111-20	20 in 1 BOTTLE, DISPENSING		
2	NDC:51655-111-84	14 in 1 BOTTLE, DISPENSING		
3	NDC:51655-111-87	6 in 1 BOTTLE, DISPENSING		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076817	05/15/2014	

Labeler - Northwind Pharmaceuticals (036986393)

Registrant - Northwind Pharmaceuticals (036986393)

Establishment

Name	Address	ID/FEI	Business Operations
Northwind Pharmaceuticals		036986393	repack(51655-111)

Revised: 11/2014

Northwind Pharmaceuticals