DBL™ SULFAMETHOXAZOLE AND TRIMETHOPRIM CONCENTRATE INJECTION BP

**Description**
DBL™ Sulfamethoxazole and Trimethoprim Concentrate Injection BP is an antibacterial combination product, containing 16 mg Trimethoprim BP and 80 mg Sulfamethoxazole BP per mL in a 40 percent propylene glycol vehicle. The solution is clear and has a pH of approximately 10.

**Pharmacology**
Sulfamethoxazole/trimethoprim interferes with the bacterial synthesis of tetrahydrofolic acid, an essential stage in the production of thymidine, purines and subsequently nucleic acids. Sulfamethoxazole inhibits the formation of dihydrofolic acid from p-aminobenzoic acid; trimethoprim inhibits the action of the enzyme dihydrofolate reductase, thus preventing the synthesis of tetrahydrofolic acid from dihydrofolic acid. Thus the combination of trimethoprim and sulfamethoxazole blocks two consecutive steps within the bacterial metabolic pathway of the biosynthesis of nucleic acids and proteins.

Sulfamethoxazole/trimethoprim usually shows in vitro activity against the following gram-negative and gram-positive organisms, eg E. coli, Neisseria, Salmonella, Klebsiella-Enterobacter, Shigella, Vibrio cholerae, Bordetella pertussis, Streptococcus, Staphylococcus, Pneumococcus, Haemophilus influenzae and Proteus.

Sulfamethoxazole/trimethoprim is also active against the protozoan Pneumocystis carinii. However, Mycobacterium tuberculosis, Treponema pallidum, Mycoplasma and Pseudomonas aeruginosa are frequently resistant to sulfamethoxazole/trimethoprim.

**Pharmacokinetics**
Concentrations of at least 0.5 microgram/mL trimethoprim and 20 microgram/mL sulfamethoxazole are reached within 30 minutes after the start of an infusion and are maintained for at least 12 hours. Mean peak steady-state serum concentrations of approximately 9 and 105 micrograms/mL of trimethoprim and sulfamethoxazole, respectively, are reached after intravenous (IV) infusion of 160 mg trimethoprim and 800 mg sulfamethoxazole every 8 hours in adults with normal renal function. Steady-state trough concentrations reached with this intravenous (IV) dose are approximately 6 microgram/mL of trimethoprim and 70 microgram/mL of sulfamethoxazole. The administration of a trimethoprim/sulfamethoxazole ratio of 1:5 achieves trimethoprim/sulfamethoxazole concentrations in the blood of about 1:20.

Sulfamethoxazole/trimethoprim is widely distributed into body tissues. Sulfamethoxazole is distributed mainly in the extracellular body fluids while trimethoprim, which has lipophilic properties, concentrates in the tissues. Approximately 44% of trimethoprim and 70% of sulfamethoxazole are protein bound in the blood.

Sulfamethoxazole/trimethoprim is metabolised in the liver. Trimethoprim is metabolised to oxide and hydroxylated metabolites, while sulfamethoxazole is acetylated and conjugated with glucuronic acid. Sulfamethoxazole/trimethoprim is rapidly excreted in the urine.

**Indications**
Parenteral administration of sulfamethoxazole/trimethoprim is indicated where oral dosage is not desirable or practical, eg pre- and post-operative infections associated with surgery, trauma or gynaecology; septicaemia and other infections due to sensitive organisms such as typhoid and paratyphoid.

**Contraindications**
Sulfamethoxazole/trimethoprim is contraindicated in patients with a history of drug-induced immune thrombocytopenia with use of trimethoprim and/or sulphonamides and in patients showing marked liver parenchymal damage, blood dyscrasias and severe renal insufficiency, where repeated measurements of the plasma concentrations cannot be performed. It should not be given to patients...
with known hypersensitivity to trimethoprim or sulfonamides or with documented megaloblastic anaemia secondary to folate deficiency.

Premature babies and newborn babies during the first eight weeks of life should not be given sulfamethoxazole/trimethoprim, as sulfamethoxazole may interfere with the serum albumin-binding of bilirubin to produce kernicterus.

History of sulfonamide or trimethoprim sensitivity.

Treatment of streptococcal pharyngitis.

**Precautions**

Fatalities, although rare, have occurred due to severe reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anaemia and other blood dyscrasias. Sulfamethoxazole/trimethoprim should be discontinued if a skin rash appears. Clinical signs such as rash, sore throat, fever, arthralgia, cough, shortness of breath, pallor, purpura or jaundice may be early indications of serious reactions.

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/trimethoprim.

DBL™ Sulfamethoxazole and Trimethoprim Concentrate Injection BP contains sodium metabisulfite, a sulfite that may cause allergic-type reactions, including anaphylaxis and life-threatening or less severe asthmatic episodes, in certain susceptible individuals. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low; such sensitivity appears to occur more frequently in asthmatic than in nonasthmatic individuals.

Use in the elderly: The use of sulfamethoxazole/trimethoprim in elderly patients carries an increased risk of severe adverse reactions. In rare instances fatalities have occurred. The risk of severe adverse reactions is particularly greater when complicating conditions exist, eg impaired kidney and/or liver function, or concomitant use of other drugs. Severe skin reactions, or generalised bone marrow suppression (see Adverse Reactions) or a specific decrease in platelets (with or without purpura) 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. Appropriate dosage adjustments should be made for patients with impaired kidney function (see Dosage and Administration).

In view of the increased risk of severe adverse reactions in the elderly, consideration should be given to whether sulfamethoxazole/trimethoprim is the antibacterial of choice in this age group.

Use in treatment of "Pneumocystis carinii" pneumonitis in patients with Acquired Immunodeficiency Syndrome (AIDS): Because of their unique immune dysfunction, AIDS patients may not tolerate or respond to sulfamethoxazole/trimethoprim in the same manner as non-AIDS patients. The incidence of side effects, particularly rash, fever, neutropenia, thrombocytopenia, raised liver enzymes and leucopenia necessitating cessation of therapy, with sulfamethoxazole/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/trimethoprim in non-AIDS patients. Such adverse effects have occurred in up to 80% of AIDS patients receiving the drug, usually during the second week of therapy. The exact mechanism(s) of this increased risk of sulfamethoxazole/trimethoprim toxicity has not been determined, but may be immunologically based. These adverse effects usually recur following rechallenge with the drug, although cautious desensitisation has been performed successfully in some patients in whom continued sulfamethoxazole/trimethoprim therapy was considered necessary. Some evidence indicates that sulfamethoxazole/trimethoprim may be better tolerated in HIV-infected children than adults. Adverse effects are usually less severe in patients receiving the drug for prophylaxis of *Pneumocystis carinii* pneumonia compared with those receiving sulfamethoxazole/trimethoprim for treatment of the disease.
Use in glucose-6-phosphate dehydrogenase deficiency: In individuals with glucose-6-phosphate dehydrogenase deficiency, haemolysis may occur. This may be dose related.

Antibiotic associated pseudomembranous colitis has been reported with many antibiotics including sulfamethoxazole and trimethoprim. A toxin produced with *Clostridium difficile,* appears to be the primary cause. The severity of the colitis may range from mild to life threatening. It is important to consider this diagnosis in patients who develop diarrhoea or colitis in association with antibiotic use (this may occur up to several weeks after cessation of antibiotic therapy). Mild cases usually respond to drug discontinuation alone. However, in moderate to severe cases appropriate therapy with a suitable oral antibacterial agent effective against *Clostridium difficile* should be considered. Fluids, electrolytes and protein replacement should be provided when indicated. Drugs which delay peristalsis eg, opiates and diphenoxylate with atropine (Lomotil) may prolong and/or worsen the condition and should not be used.

As with other sulfonamide preparations, critical appraisal of benefit versus risk should be made in patients with liver damage, renal damage, urinary obstruction, blood dyscrasias, allergies or bronchial asthma. In renal impairment, a reduced or less frequent dosage is recommended in order to avoid accumulation of trimethoprim in the blood. Non-ionic diffusion is the main factor in the renal handling of trimethoprim, and as renal failure advances, trimethoprim excretion decreases. For such patients, serum assays are necessary.

Urinalysis with careful microscopic examination and renal function tests should be performed frequently, particularly for those patients with impaired renal function. Adequate fluid intake must be maintained in order to prevent crystalluria and stone formation. In patients with renal impairment, a reduced or less frequent dosage is recommended to avoid accumulation of trimethoprim in the blood.

Because of the possible interference with folate metabolism, regular blood counts are advisable in patients on long-term therapy, in those who are pre-disposed to folate deficiency (i.e. the elderly, chronic alcoholics and those with rheumatoid arthritis), in malabsorption syndromes, malnutrition states or during the treatment of epilepsy with anticonvulsant drugs such as phenytoin, primidone and barbiturates. Folic acid may be administered during sulfamethoxazole/trimethoprim therapy and will not interfere with the drugs antibacterial effect. Megaloblastic anaemia and occasionally neutropenia and thrombocytopenia may be reversed by administration of calcium leucovorin (folinic acid). If signs of bone marrow suppression occur in patients receiving sulfamethoxazole/trimethoprim, leucovorin may be administered.

The possibility of superinfection with a non-sensitive organism should be borne in mind.

**Use in Pregnancy**

Category C*. Sulfonamides may cause kernicterus in babies during the first month of life by displacing bilirubin from plasma albumin. Sulfonamides should therefore be avoided as far as possible during the last month of pregnancy. Trimethoprim may interfere with folic acid metabolism and animal experiments have shown that administration of very high doses of trimethoprim during organ development may give rise to birth defects typical of folic acid antagonism. If a trimethoprim-sulfonamide combination is given during pregnancy, folic acid supplementation may be required.

*Category C = Drugs which, owing to their pharmacological effects, have caused or may be suspected of causing, harmful effects on the human fetus or neonate without causing malformations. These effects may be reversible.

**Use in Lactation**

Both trimethoprim and sulfamethoxazole are excreted in breast milk at concentrations comparable or somewhat lower than those in the blood. Although the quantity of sulfamethoxazole/trimethoprim ingested by a breast-fed infant is small, it is recommended that the age of the infant be considered and the possible risks be balanced against the expected therapeutic effect.

**Interactions**

Methotrexate:* Sulfonamides such as sulfamethoxazole may displace methotrexate from protein binding sites, thereby increasing free methotrexate levels. Cases of pancytopenia have been reported in patients taking the combination of sulfamethoxazole/trimethoprim and methotrexate.
PABA or its derivatives: may antagonise the antibacterial effects of sulfamethoxazole.

Urinary acidifiers: Increased sulfamethoxazole blood levels may occur in patients who are also receiving urinary acidifiers, oral anticoagulants, phenylbutazone, oxyphenbutazone and indomethacin.

Warfarin: Anticoagulant activity may be increased by concurrent treatment with Sulfamethoxazole/trimethoprim.

Phenytoin: Increased effects and side effects of phenytoin (folate deficiencies) could occur when Sulfamethoxazole/trimethoprim is given concurrently.

Cross sensitisation may exist between sulfamethoxazole/trimethoprim and some antithyroid agents, diuretics (acetazolamide and the thiazides) and oral hypoglycaemic drugs.

Sulphonylureas: Concomitant use may result in potentiation of hypoglycaemia in occasional patients.

Diuretics: An increased incidence of thrombocytopenia is reported when this combination is used in the elderly.

Cyclosporin:– Deterioration in renal function in patients with renal transplants.

Pyrimethamine:– Occasional reports suggest that patients receiving pyrimethamine as malarial prophylaxis at doses in excess of 25 mg weekly may develop megaloblastic anaemia should sulfamethoxazole/trimethoprim be prescribed concurrently.

Digoxin:– Concomitant use of trimethoprim with digoxin has been shown to increase plasma digoxin levels in a proportion of elderly patients.

Others: When trimethoprim is administered simultaneously with drugs that form cations at physiological pH, and are also partly excreted by active renal secretion (eg procainamide, amantadine), there is the possibility of competitive inhibition of this process which may lead to an increase in plasma concentration of one or both of the drugs.

**Effects on laboratory tests**

Two laboratory procedures, namely the *Lactobacillus casei* serum folate assay and the *L. leishmanii* serum vitamin B12 assay are affected by sulfamethoxazole/trimethoprim.

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

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

**Adverse Reactions**

Fatalities, although rare, have occurred due to severe reactions including Stevens-Johnson syndrome, toxic epidermal necrosis, fulminant hepatic necrosis, agranulocytosis, aplastic anaemia and other blood dyscrasias. Sulfamethoxazole/trimethoprim should be discontinued if a skin rash appears. Clinical signs such as rash, sore throat, fever, arthralgia, cough, shortness of breath, pallor, purpura or jaundice may be early indications of serious reactions.

Adverse reactions have been reported in approximately 5-7% of patients treated in the published literature. In general, the adverse reactions correspond to those of a sulfonamide of moderately low toxicity.
Gastrointestinal:- Nausea and vomiting are the most frequent gastrointestinal reactions to sulfamethoxazole/trimethoprim, but glossitis, stomatitis, abdominal pain, pancreatitis, pseudomembranous colitis and diarrhoea have also been reported.

Haematological:- Haematological changes have been observed in some patients, particularly the elderly. The great majority of these changes were mild, asymptomatic and proved reversible on withdrawal of the drug. The reported changes consist primarily of neutropenia and thrombocytopenia. Leucopenia, eosinophilia, megaloblastic anaemia, methaemoglobinemia, hypothyroidism, aplastic and haemolytic anaemia, purpura, agranulocytosis and bone marrow depression have been observed less frequently. Haematological toxicity may occur with increased frequency in folate-depleted patients including geriatric, malnourished, alcoholic, pregnant or debilitated patients; in patients receiving anti-folates (eg phenytoin or methotrexate) or diuretics; in patients with haemolytic or impaired renal function; and in patients receiving sulfamethoxazole/trimethoprim in high dosages and/or for prolonged periods (eg longer than 6 months). In geriatric patients receiving some diuretics (principally thiazides) and sulfamethoxazole/trimethoprim concomitantly, an increased incidence of thrombocytopenia with purpura has been reported. The risk of leucopenia, neutropenia and thrombocytopenia also appear to be increased in patients with AIDS.

Sensitivity reactions:- Several cases of Stevens-Johnson syndrome (erythema multiforme bullosa) and Lyell’s syndrome (toxic epidermal necrosis) have been reported. Together with exfoliative dermatitis, serum sickness and allergic myocarditis, these are the most severe allergic reactions reported with sulfonamides alone, or in combination with trimethoprim. Other reported allergic and anaphylactoid reactions include anaphylaxis, arthralgia, erythema multiforme, Schönlein-Henoch purpura, pruritus, urticaria, periorbital oedema, corneal ring infiltrates, conjunctival and scleral redness and oedema, and photosensitivity. Mild to moderate rashes, when they occur, usually appear within 7-14 days after initiation of sulfamethoxazole/trimethoprim. Rashes are generally erythematous, maculopapular, morbilliform, and/or pruritic. Generalised pustular dermatitis and fixed drug eruption have also been reported. Patients with AIDS appear to be at particular risk of developing rash (usually diffuse, erythematous and maculopapular) during sulfamethoxazole/trimethoprim therapy.

Hepatic:- Hepatic changes (as indicated by abnormal elevations in alkaline phosphatase and serum transaminase levels) including hepatic necrosis have been reported rarely and may be fatal. Jaundice rarely occurs and has usually been mild and transient, frequently occurring in patients with a past history of infectious hepatitis. Elevation of bilirubin levels has also been reported.

Genitourinary:- Dysuria, oliguria, anuria, haematuria, urgency and functional kidney changes (as indicated by abnormal elevations in serum urea, serum creatinine and urine protein concentrations) have been reported occasionally. Renal failure, interstitial nephritis and toxic nephrosis have been reported. Crystalluria and stone formation have occurred in patients receiving sulfamethoxazole/trimethoprim. Diuresis has occurred rarely in patients receiving sulfonamides.

Central nervous system:- Adverse nervous system effects of sulfamethoxazole/trimethoprim include headache, insomnia, fatigue, apathy, nervousness, muscle weakness, ataxia, vertigo, tinnitus, peripheral neuritis, mental depression, aseptic meningitis, seizures and hallucinations. Tremor and other neurologic manifestations (eg ataxia, ankle clonus, apathy) developed during sulfamethoxazole/trimethoprim therapy in several patients with AIDS; although such manifestations have also been associated with the underlying disease process, they resolved in these patients within 2-3 days after discontinuing the drug.

Local effects:- Pain, local irritation, inflammation, and thrombophlebitis may occasionally occur with intravenous sulfamethoxazole/trimethoprim, especially if extravasation of the drug occurs.

Miscellaneous:- Other adverse effects reported with sulfamethoxazole/trimethoprim include drug fever, chills, myalgia, pulmonary infiltrates, cough, shortness of breath, hypotension, periarteritis nodosa and a positive lupus erythematosus phenomenon. Vision problems, alopecia and epistaxis have been reported rarely.

**Dosage and Administration**
DBL™ Sulfamethoxazole and Trimethoprim Concentrate Injection BP must be diluted prior to administration. Sulfamethoxazole/trimethoprim should be administered intravenously only in the form of an infusion solution, and may not be injected undiluted either intravenously or direct into the infusion tube.

DBL™ Sulfamethoxazole and Trimethoprim Concentrate Injection BP may be mixed only with the following infusion solutions:

- 5% Glucose Injection
- 4% Glucose/0.18% Sodium Chloride Injection
- 0.9% Sodium Chloride
- 10% Glucose Injection
- 2.5% Glucose/0.45% Sodium Chloride Injection
- 0.45% Sodium Chloride Injection
- 10% Dextran 40 in 5% Glucose
- 6% Dextran 70 in 0.9% Sodium Chloride Injection
- Hartmann's Injection

No other agent should be added to or mixed with the infusion.

It is important to adhere to the following minimum dilution scheme, which is based on a proportion of 1 mL DBL™ Sulfamethoxazole and Trimethoprim Concentrate Injection BP to 25-30 mL infusion fluid. Add one ampoule (5 mL) to 125 mL infusion solution; two ampoules (10 mL) to 250 mL infusion solution; or three ampoules (15 mL) to 500 mL infusion solution or an equivalent dilution.

The prepared infusion should be shaken well to ensure thorough mixing. Should visible turbidity or crystallisation appear in the solution during its preparation or infusion, it must be discarded and replaced by a freshly prepared solution.

It is recommended that infusion of sulfamethoxazole/trimethoprim be commenced within half an hour of preparation and the duration of infusion should not exceed 1.5 hours. However, this should be balanced against the fluid requirements of the patient.

To reduce microbiological hazards the prepared diluted solution should in any case be used as soon as practicable after preparation and within 24 hours. Do not refrigerate prepared solution.

**Dosage for Adults and Children over 12 years**
Standard Dose: 10 mL diluted and infused twice daily.
For severe infections: 15 mL diluted and infused twice daily.

**Dosage for Children to 12 years**
The recommended dosage is approximately 6 mg trimethoprim and 30 mg sulfamethoxazole per kg bodyweight per day, divided into two equal doses, morning and evening. As a guide, the following doses of DBL™ Sulfamethoxazole and Trimethoprim Concentrate Injection BP may be used:

- 2 months to 5 months: 1.25 mL diluted and infused twice daily.
- 6 months to 5 years: 2.5 mL diluted and infused twice daily.
- 6 years to 12 years: 5 mL diluted and infused twice daily.

The recommended dosage for patients with documented *Pneumocystis carinii* pneumonitis is 20 mg/kg trimethoprim and 100 mg/kg sulfamethoxazole per 24 hours given in equally divided doses every 6 hours for 14 days.

**Dosage in Reduced Renal Function**
In patients with impaired renal function, the dosage and/or frequency of administration of sulfamethoxazole/trimethoprim needs to be modified.

The following dosage regimens have been published for the administration of sulfamethoxazole/trimethoprim tablets to patients with reduced kidney function. In view of the close similarity of plasma levels of trimethoprim and sulfamethoxazole when sulfamethoxazole/trimethoprim is given orally and
intravenously, there is no reason to suppose that these regimens cannot be followed with DBL™ Sulfamethoxazole and Trimethoprim Concentrate Injection BP

**Criteria of Kidney Function**

<table>
<thead>
<tr>
<th>Creatinine Clearance mL/min</th>
<th>Serum Creatinine Micromol/L (a)</th>
<th>Recommended Dosage Regimens</th>
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<tbody>
<tr>
<td>Above 25</td>
<td>Men &lt; 260; Women &lt; 170</td>
<td>One Standard Dose for Adults 160 mg TMP + 800 mg SMX</td>
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<tr>
<td>25 - 15</td>
<td>Men 260 to 600; Women 170 to 400</td>
<td>Dosage as for patients with normal kidney function, ie 1 standard dose every 12 hours for up to 14 days; thereafter half standard dose every 12 hours; no necessity of control analyses of drugs in plasma.</td>
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<tr>
<td>Below 15</td>
<td>Men &gt; 600; Women &gt; 400</td>
<td>One standard dose every 12 hours for 3 days; thereafter one standard dose every 24 hours for as long as allowed by control analyses (b).</td>
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<tr>
<td></td>
<td></td>
<td>Until further experience is gained, the combination should be given only if patients can undergo haemodialysis when necessary (c); under this condition one standard dose may be administered every 24 hours as long as allowed by control analyses (b).</td>
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</tbody>
</table>

**Recommended Dosage Regimens**

One Standard Dose for Adults 160 mg TMP + 800 mg SMX

Dosage as for patients with normal kidney function, ie 1 standard dose every 12 hours for up to 14 days; thereafter half standard dose every 12 hours; no necessity of control analyses of drugs in plasma.

One standard dose every 12 hours for 3 days; thereafter one standard dose every 24 hours for as long as allowed by control analyses (b).

Until further experience is gained, the combination should be given only if patients can undergo haemodialysis when necessary (c); under this condition one standard dose may be administered every 24 hours as long as allowed by control analyses (b).

**Duration of treatment**

DBL™ Sulfamethoxazole and Trimethoprim Concentrate Injection BP should be used ONLY during such periods as the patient is unable to accept oral therapy. In general, administration is unlikely to be required for more than a few days, and it is recommended that it be restricted to no more than three successive days.

**Overdosage**

**Symptoms**

Overdosage with sulfamethoxazole/trimethoprim may produce symptoms of nausea, vomiting, mental and visual disturbances, petechiae, purpura, pyrexia, haematuria and crystalluria. Blood dyscrasias and jaundice are late complications.
**Treatment**

Stop therapy. Force fluids orally or parenterally if renal function is normal. In extreme overdosage in patients with impaired renal function, consider haemodialysis which is moderately effective in removing sulfamethoxazole and trimethoprim. Peritoneal dialysis is ineffective.

No known antidote for sulfonamide poisoning exists, however, calcium folinate (the equivalent of 3 mg to 6 mg folinic acid intramuscularly, for 5 to 7 days) is an effective antidote for adverse effects in the haemopoietic system caused by trimethoprim.

**Storage**

Store below 30°C. Do not refrigerate. Protect from light.

If stored at low temperatures precipitation may occur, and solutions in which precipitation has occurred should be discarded.

**Compatibilities**

DBL™ Sulfamethoxazole and Trimethoprim Concentrate Injection BP has been found to be stable for 24 hours at room temperature under fluorescent light when admixed with the following solutions at a dilution of 1 in 25 and 1 in 35.

- 5% Glucose Injection
- 4% Glucose/0.18% Sodium Chloride Injection
- 0.9% Sodium Chloride Injection
- 10% Glucose Injection
- 2.5% Glucose/0.45% Sodium Chloride Injection
- 0.45% Sodium Chloride Injection
- Dextran 70 6% in 0.9% Sodium Chloride Injection
- Dextran 40 10% in 5% Glucose

No other agent should be added to or mixed with the infusion.

When admixed with Hartmann's Injection, DBL™ Sulfamethoxazole and Trimethoprim Concentrate Injection BP has been found to be stable for 8 hours at a 1 in 25 dilution and for 24 hours at a 1 in 35 dilution.

**Medicine Classification**

Prescription Medicine

**Presentation**

DBL™ Sulfamethoxazole and Trimethoprim Concentrate Injection BP is available in the following strength and pack:-

<table>
<thead>
<tr>
<th>Strength</th>
<th>Pack</th>
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<tbody>
<tr>
<td>400 mg Sulfamethoxazole</td>
<td>5 x 5 mL ampoule</td>
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<tr>
<td>and 80 mg Trimethoprim</td>
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**Name and Address**

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**Date of Preparation**

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