Alert	Not be used in infants < 4 weeks of age. Dose is expressed as trimethoprim (TMP) component. The Antimicrobial Stewardship Team recommends this drug is listed under the following category: Neonates: Restricted; Infants > 4 weeks of age: Oral — unrestricted and IV — restricted.
Indication	Prophylaxis of urinary tract infections (UTI). Treatment of mild–severe infections including UTI and acute otitis media. Prophylaxis in HIV-exposed infants
Action	Sulfamethoxazole is a sulfonamide that prevents the formation of dihydrofolic acid, a bacterial compound necessary for survival. Trimethoprim is a synthetic antibiotic that interferes with the production of folic acid by dihydrofolate reductase.
Drug Type	Sulfonamide with antifolate
Trade Name	Oral: Bactrim Oral Suspension [Roche]; Septrin Sugar Free Suspension [Aspen] IV: DBL Sulfamethoxazole 400 mg and Trimethoprim 80 mg Concentrate Injection BP [Hospira]
Presentation	Oral liquid: Trimethoprim 8 mg/mL and sulfamethoxazole 40 mg/mL, 100 mL IV ampoule: Trimethoprim 16 mg/mL and sulfamethoxazole 80 mg/mL 5mL ampoule
Dosage / Interval	**Dosage recommendations are based on trimethoprim component.** **UTI prophylaxis** PO: 2 mg TMP/kg/dose daily or 5 mg TMP/kg/dose twice weekly. **Prophylaxis in HIV-exposed infants < 6 months of age** To commence from 4–6 weeks of age at a dose of 20 mg trimethoprim once daily (not per kg basis) (equates to 2.5 mL oral liquid daily) **Treatment of mild–severe infections (e.g. UTI, acute otitis media)** Mild to moderate infections PO: 3–6 mg TMP/kg/dose 12 hourly (AAP Guidelines 2011). Severe infections IV: 2–3 mg TMP/kg/dose 6 hourly.
Maximum daily dose	
Route	PO, IV
Preparation/Dilution	PO: Oral liquid does not require preparation IV: Draw up 2 mL (32 mg trimethoprim and 80 mg sulfamethoxazole) and add 48 mL of sodium chloride 0.9%, glucose 5% or glucose 10% to make a final volume of 50mL with a concentration of 0.64 mg/mL of TMP. For severely fluid restricted neonates: Draw up 2 mL (32 mg trimethoprim and 80 mg sulfamethoxazole) and add 18 mL of glucose 5% to make a final volume of 20mL with a final concentration of 3.2 mg/mL of TMP and infuse ONLY VIA A CENTRAL LINE as it is an alkaline solution. Also, follow up with a flush of up to 20 mL.
Administration	PO: Administer with feeds. Shake well before measuring dose. IV: Infuse over 60–90 minutes. Follow-up with a flush of up to 20 mL.
Monitoring	Watch for skin reactions and blood dyscrasias. Monitor renal function and full blood count.
Contraindications	Hypersensitivity to sulfonamides or trimethoprim. Infants < 4 weeks of age (manufacturer says< 8 weeks).
Precautions	Use with caution in renal impairment. Dosage adjustment is required in renal impairment. Suggested adjustment(Product Info) is as follows (MIMS):

Renal Impairment Dose Adjustments	
CrCl (mL/min)	Dosage
Above 25	Standard regimen
15 to 25	One-half the standard regimen
Below 15	Not recommended

	Concomitant use of potassium sparing diuretics can lead to hyperkalaemia. In individuals with glucose-6-phosphate dehydrogenase deficiency, haemolysis may occur.
Drug Interactions	Risk of prolonged QT interval with concurrent use of chloral hydrate, erythromycin and fluconazole.
Adverse Reactions	Gastrointestinal upset (vomiting, diarrhoea). Severe dermatologic reactions, blood dyscrasias, hepatotoxicity. Prolonged use may result in fungal or bacterial superinfection. Prolonged QT interval, torsades de pointes, ventricular tachycardias have been reported in adults.
Compatibility	Fluids: Glucose 5%, glucose 10%, sodium chloride 0.9%, sodium chloride 0.45% Y site: Aciclovir, amino acid solutions, amphotericin B liposomal, lipid emulsions, metronidazole, milrinone, morphine, pancuronium, piperacillin-tazobactam, vecuronium, zidovudine.
Incompatibility	Y site: Amikacin, aminophylline, amiodarone, amphotericin b lipid complex, ampicillin, atropine, calcium chloride, calcium gluconate, cefazolin, cefotaxime, ceftazidime, ceftriaxone, chloramphenicol, clindamycin, dexamethasone, diazepam, diazoxide, digoxin, dobutamine, dopamine, adrenaline (epinephrine), erythromycin, fentanyl, fluconazole, folic acid, furosemide, ganciclovir, gentamicin, heparin, hydralazine, hydrocortisone, indometacin, insulin, isoprenaline, ketamine, lactated ringer's, lidocaine (lignocaine), methylprednisolone, midazolam, multiple vitamins injection, noradrenaline (norepinephrine), benzylpenicillin, phenobarbital (phenobarbitone), phenytoin, piperacillin, potassium chloride, propranolol, pyridoxine, ranitidine, sodium bicarbonate, tobramycin, urokinase, vancomycin.
Stability	IV: Start infusion immediately after diluting – infusion must be completed within 2 hours of preparation. Monitor for precipitation, particularly with concentrated infusions.
Storage	Store IV and oral preparations below 30°C. Do not refrigerate. Protect from light.
Special Comments	
Evidence summary	Refer to Full version
References	Refer to Full version

Original version Date: 24/08/2016	**Author: NMF Consensus Group**
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