

Alert	The Antimicrobial Stewardship Team has listed this drug under the following categories : Unrestricted- treatment up to 48 hours Obtain approval from the Infectious Diseases Team– treatment > 48 hours																								
Indication	Treatment of suspected or proven gram negative infection. Often used in combination with a beta-lactam antibiotic as empiric therapy for sepsis in the newborn.																								
Action	Bactericidal agent that acts by inhibiting protein synthesis in susceptible bacteria.																								
Drug Type	Aminoglycoside																								
Trade Name	DBL gentamicin, Gentamicin BP, Gentamicin Pfizer																								
Presentation	10 mg/mL ampoule- paediatric strength 80 mg/2 mL ampoule- adult strength																								
Dosage / Interval	<p>5mg/kg/dose. Dosing interval as per Tables below</p> <table border="1"> <thead> <tr> <th colspan="2">Method (First 2 doses)</th> <th rowspan="2">Interval (hours)</th> </tr> <tr> <th>Corrected Gestational Age/Postmenstrual Age</th> <th>Route</th> </tr> </thead> <tbody> <tr> <td>< 30⁺⁰ weeks</td> <td>IV/IM</td> <td>48 hourly</td> </tr> <tr> <td>30⁺⁰–34⁺⁶ weeks</td> <td>IV/IM</td> <td>36 hourly</td> </tr> <tr> <td>≥ 35⁺⁰ weeks</td> <td>IV/IM</td> <td>24 hourly</td> </tr> </tbody> </table> <p>Subsequent dose interval is based on a gentamicin concentration at 22 hours after the administration of the 2nd dose as indicated in the table below.</p> <table border="1"> <thead> <tr> <th>Gentamicin level</th> <th>Interval</th> </tr> </thead> <tbody> <tr> <td>≤ 1.2 mg/L</td> <td>Every 24 hours after previous dose</td> </tr> <tr> <td>1.3 mg/L – 2.6 mg/L</td> <td>Every 36 hours after previous dose</td> </tr> <tr> <td>2.7 mg/L – 3.5 mg/L</td> <td>Every 48 hours after previous dose</td> </tr> <tr> <td>≥ 3.6 mg/L</td> <td>Hold dose, repeat concentration 24 hours later</td> </tr> </tbody> </table> <p>Gentamicin monitoring is required ONCE only, except when renal function is compromised. Refer to monitoring section below.</p>	Method (First 2 doses)		Interval (hours)	Corrected Gestational Age/Postmenstrual Age	Route	< 30 ⁺⁰ weeks	IV/IM	48 hourly	30 ⁺⁰ –34 ⁺⁶ weeks	IV/IM	36 hourly	≥ 35 ⁺⁰ weeks	IV/IM	24 hourly	Gentamicin level	Interval	≤ 1.2 mg/L	Every 24 hours after previous dose	1.3 mg/L – 2.6 mg/L	Every 36 hours after previous dose	2.7 mg/L – 3.5 mg/L	Every 48 hours after previous dose	≥ 3.6 mg/L	Hold dose, repeat concentration 24 hours later
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Preparation/Dilution	10 mg/mL- paediatric strength: Add 1 mL (10 mg) of gentamicin to 4 mL sodium chloride 0.9% to make a final volume of 5 mL with a concentration of 2 mg/mL. 80 mg/2 mL- adult strength: Add 1 mL (40 mg) of gentamicin to 19 mL sodium chloride 0.9% to make a final volume of 20 mL with a concentration of 2 mg/mL.																								
Administration	IV: Slow infusion over 5 minutes. IM: Variable absorption by the IM route, use only when IV route is not available. Gentamicin is inactivated by penicillins and cephalosporins so should not be mixed in the same solution or administered simultaneously. Ensure the line is adequately flushed if administered consecutively.																								
Monitoring	Routine therapeutic drug monitoring for ≤ 48 hours duration of therapy is not necessary unless renal function is impaired. For therapy > 48 hours, perform gentamicin concentration 22 hours after the 2 nd dose and determine the dose interval as described in the dosage section. Further gentamicin concentrations are not necessary unless renal function is impaired. Renal impairment: Perform gentamicin concentration 22 hours after every dose to determine the dose interval. Peak concentration may be important if an organism has a high minimum inhibitory concentration (MIC) – speak with your microbiologist. Target peak concentration: 5–12 mg/L.																								

	Peak concentration should be drawn at 30 minutes post dose.
Contraindications	Concurrent therapy with other ototoxic or nephrotoxic drugs.
Precautions	CAUTION in patients with pre-existing renal impairment, auditory or vestibular impairment, hypocalcaemia, depressed neuromuscular transmission.
Drug Interactions	Gentamicin should not be mixed with penicillins parenterally as inactivation occurs. Ensure line is adequately flushed between antibiotics.
Adverse Reactions	<p>Toxicity is rare in the newborn but can include:</p> <ol style="list-style-type: none"> 1. Nephrotoxicity- Associated with excessive accumulation of gentamicin. The initial symptoms may be due to renal tubular concentrating defect. These include excessive losses of sodium, calcium and magnesium. This may progress to proteinuria, increased urea, oliguria, increased serum creatinine. Renal impairment is most usually reversible. 2. Ototoxicity. Primary vestibular but also auditory toxicity. Associated with excessive high plasma gentamicin concentrations and duration of therapy. Effects often irreversible. 3. Neuromuscular blockade- Muscular paralysis and respiratory failure may occur particularly when used with other neuromuscular blockers such as pancuronium. 4. Hypersensitivity- Very rare – rash, urticaria, fever, laryngeal oedema, eosinophilia. <p>NEPHROTOXICITY AND OTOTOXICITY ARE MORE PRONOUNCED WITH ADDITION OF OTHER NEPHROTOXIC/OTOTOXIC AGENTS SUCH AS FRUSEMIDE AND VANCOMYCIN.</p>
Compatibility	<p>Fluids: Glucose 5% , glucose 10%, Hartmann's, mannitol , sodium chloride 0.9%</p> <p>Y-Site: Amino acid solutions, amifostine, amiodarone, anidulafungin, atracurium, aztreonam, bivalirudin, caspofungin, ciprofloxacin, cisatracurium, dexmedetomidine, esmolol, fluconazole, foscarnet, granisetron, hydromorphone, labetalol, linezolid, magnesium sulfate, midazolam, morphine sulfate, palonosetron, pancuronium, pethidine, potassium chloride, remifentanyl, tigecycline, vecuronium, zidovudine.</p>
Incompatibility	<p>Fluids: Fat emulsions.</p> <p>Y-site: Azathioprine, azithromycin, chloramphenicol, dexamethasone, flucloxacillin, folic acid, frusemide, ganciclovir, heparin sodium, indomethacin, pentamidine, propofol, teicoplanin.</p>
Stability	Administer immediately, discard unused portion.
Storage	Protect from light. Store below 25°C
Evidence summary	As per NeoMed Consensus Group. Refer to reference manual or electronic version.
References	As per NeoMed Consensus Group. Refer to reference manual or electronic version.

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Current Version number: 1.1	Version Date: 23/06/2016
Risk Rating: Medium	Due for Review: 08/08/2018
Approval by: JHCH CQ&PCC	Approval Date: 22/11/2016