Gentamicin
Newborn use only

2020

<table>
<tr><td>Alert</td><td>The administration of antibiotics within 1 hour of the identification of sepsis is recommended.(1)
The Antimicrobial Stewardship Team has listed this drug under the following categories :
Unrestricted – duration up to 48 hours and restricted for duration > 48 hours
Aminoglycosides can be inactivated by penicillin and cephalosporin antibiotics. As commonly co-prescribed, where feasible, give at separate sites or separate the administration time of the antibiotics.
Unregistered products from overseas available during shortages may contain preservatives.</td></tr>
<tr><td>Indication</td><td>Treatment of gram-negative infections.</td></tr>
<tr><td>Action</td><td>Bactericidal agent that acts by inhibiting protein synthesis in susceptible bacteria.</td></tr>
<tr><td>Drug type</td><td>Aminoglycoside antibiotic</td></tr>
<tr><td>Trade name</td><td>DBL gentamicin, Gentamicin BP (Pfizer)</td></tr>
<tr><td>Presentation</td><td>10 mg/mL ampoule – paediatric strength
80 mg/2 mL ampoule – adult strength
NOTE: SAS product may be considered in the event of a shortage. Consult the local pharmacy.</td></tr>
<tr><td>Dose</td><td>Dose: 5 mg/kg as follows: (2-5)
<table>
<tr><th>Corrected Gestational Age/Postmenstrual Age*</th><th>Route</th><th>Dosing interval</th><th>Drug concentration to be performed at:</th></tr>
<tr><td>< 30^{+0} weeks*</td><td>IV/IM</td><td>48 hourly</td><td>22 hours after the 2nd dose</td></tr>
<tr><td>30^{+0}–34^{+6} weeks*</td><td>IV/IM</td><td>36 hourly</td><td>22 hours after the 2nd dose</td></tr>
<tr><td>≥ 35^{+0} weeks*</td><td>IV/IM</td><td>24 hourly</td><td>22 hours after the 2nd dose</td></tr>
<tr><td>*Concurrent cyclo-oxygenase inhibitors (indomethacin or ibuprofen) (6-8)</td><td>IV/IM</td><td>Extend dosing interval by 12 hours
Example:
48 hourly to 60 hourly</td><td></td></tr>
<tr><td>Therapeutic hypothermia (9-13)</td><td>IV/IM</td><td>36 hourly</td><td>Trough concentrations prior to every dose</td></tr>
</table>
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.(3, 4)
<table>
<tr><th>22-hour Gentamicin concentration*</th><th>Interval</th></tr>
<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>
</table>
*Different to trough concentration performed prior to next dose – Refer to dose adjustment section.

Gentamicin monitoring is required ONCE only, except the duration of gentamicin therapy is greater than 7 days or with the conditions described in dose adjustment and monitoring section.</td></tr>
<tr><td>Dose adjustment</td><td>Therapeutic hypothermia –36 hourly interval.(9-13). Measure trough concentrations before every dose.
ECMO - Renal dysfunction is the main determinant. Measure trough concentration before 2nd dose.(14)
Renal impairment – Measure trough concentration before every dose.
Hepatic impairment – No specific dose adjustment.</td></tr>
<tr><td>Maximum dose</td><td></td></tr>
<tr><td>Total cumulative dose</td><td></td></tr>
</table>

Route	IV IM – only if IV access is not available.
Preparation	**10mg/mL – paediatric strength** Draw up 1mL (10mg) gentamicin and add to 4mL of sodium chloride 0.9% to make a final volume of 5mL with a concentration of 2mg/mL solution. **80mg/2 mL – adult strength** Draw up 1mL (40mg) gentamicin and add to 19mL of sodium chloride 0.9% to make a final volume of 20mL with a concentration of 2mg/mL solution.
Administration	IV - Inject slowly over 5 minutes as an IV injection.(15) IM- only given when IV route is not available as the IM absorption is variable. Administer required dose undiluted, deeply into anterolateral thigh muscle.
Monitoring	Urine output, urine analysis, blood urea, nitrogen and creatinine Monitor for anaphylaxis Trough concentrations – Target trough concentration: <2 mg/L. Repeat trough concentrations are not required routinely unless: (4) (1) duration of therapy is ≥ 7 days – In this scenario, prior to dose on day 7 and then weekly thereafter. (2) renal impairment or perinatal hypoxia with Apgar <5 at 5 minutes and/or concomitant use of other nephrotoxic agents or therapeutic hypothermia In these scenarios, perform trough concentration prior to every dose. If trough concentration ≥2 mg/L, withhold the dose, repeat trough concentrations before the subsequent dosing and discuss with infectious disease specialist/clinical microbiologist for either extended dosing interval or alternate antibiotic. Peak concentrations - Not required routinely. Target peak concentrations: 5-12 mg/L. Peak concentration should be drawn at 30 minutes post dose.
Contraindications	Hypersensitivity to aminoglycosides
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 or cephalosporins as inactivation occurs.(15) Ensure line is adequately flushed between antibiotics and if possible, stagger the time of administration of each drug so that they are separated by several hours. Avoid use with other potent diuretics, neurotoxic, nephrotoxic and neuromuscular blocking agents.(16)
Adverse reactions	Toxicity is rare in the newborn but can include: 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 usually reversible. 2. Ototoxicity. Primarily vestibular but also auditory toxicity. Associated with excessive accumulation of gentamicin 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. Nephrotoxicity and ototoxicity are more pronounced with addition of other nephrotoxic/ototoxic agents such as furosemide and vancomycin.
Compatibility	Fluids: Glucose 5% , glucose 10%, Hartmann's, sodium chloride 0.9%, Ringer's (15) Y-Site: Amino acid solutions, amifostine, amiodarone, anidulafungin, atracurium, aztreonam, bivalirudin, calcium chloride, calcium gluconate, caspofungin, ciprofloxacin, cisatracurium,

	clindamycin, dexmedetomidine, digoxin, dobutamine, esmolol, fentanyl, fluconazole, foscarnet, granisetron, hydromorphone, labetalol, linezolid, magnesium sulfate, meropenem, methylprednisolone, metronidazole, midazolam, morphine sulfate, , pancuronium, pethidine, phenobarbital sodium, potassium chloride, remifentanil, rocuronium, suxamethonium, tigecycline, vancomycin, vecuronium, zidovudine.
Incompatibility	Fluids: Fat emulsions. Y-site: Azathioprine, azithromycin, chloramphenicol, dexamethasone, flucloxacillin, folic acid, frusemide, ganciclovir, heparin sodium, indomethacin, pentamidine, propofol, teicoplanin. Note: Do not mix together with penicillins or cephalosporins.
Stability	Administer immediately, discard unused portion.
Storage	Protect from light. Store below 25°C
Excipients	DBL Gentamicin: Disodium edetate Pfizer Gentamicin: Disodium edetate, sodium hydroxide, sulfuric acid.
Special comments	
Evidence	Refer to full version.
Practice points	Refer to full version.
References	Refer to full version.

VERSION/NUMBER	**DATE**
Original version 1.0	21/10/2015
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