MONOGRAPH

Gentamicin (Intravenous) Monograph - Paediatric

Scope (Staff):	Medical, Pharmacy, Nursing
Scope (Area):	All Clinical Areas

Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this DISCLAIMER

QUICKLINKS

DRUG CLASS

Aminoglycoside antibiotic.[1-3]

Gentamicin is a High Risk Medicine.

INDICATIONS AND RESTRICTIONS

IV: Monitored (orange) antibiotic

Gentamicin is indicated for use as per the indications stipulated in Formulary One. For any other use, phone approval must be obtained from ChAMP before prescribing as per the Children's Antimicrobial Management Program (ChAMP) Policy.

CONTRAINDICATIONS

- Hypersensitivity to gentamicin, any aminoglycoside (e.g. tobramycin or amikacin) or any component of the formulation.[2-7]
- History of vestibular or auditory toxicity due to use of an aminoglycoside. See 'Monitoring' section.[2]

PRECAUTIONS

- Use gentamicin with caution in patients with renal impairment. Reduce the dose of gentamicin as recommended in 'Dose Adjustment' and seek infectious diseases, ChAMP or pharmacy advice. Risk factors for nephrotoxicity include duration of treatment, high plasma concentrations, dehydration and treatment with other nephrotoxic medications.[2]
- Use gentamicin with caution in patients with neuromuscular disease e.g. myasthenia gravis, as the risk of muscle weakness and respiratory depression is increased.[2, 8]
- There is an increased risk of neuromuscular adverse effects when used in patients with hypocalcaemia, hypermagnesemia and patients undergoing general anaesthesia or receiving large transfusions of citrated blood.[2, 3, 8]
- Ototoxicity (both auditory and vestibular) may occur with gentamicin use and may be irreversible.[5, 8, 9]
- Some brands of gentamicin contain sodium metabisulfite which may cause an allergic reaction in some people.[4, 7, 10]
- Gentamicin susceptibility to *Pseudomonas aeruginosa* is no longer reported in line with international antimicrobial testing authorities, tobramycin will be tested and reported instead.

FORMULATIONS

Listed below are products available at PCH, other formulations may be available, check with pharmacy if required:

- 80 mg/2 mL Vial

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates: Refer to Neonatal Medication Protocols

Dosing in Overweight and Obese Children: Dosing should be based on adjusted body weight for overweight or obese children.[1, 2]

IV/IM:

Usual dose:

- **Children ≥ 4 weeks old:** 7 mg/kg/dose (to a maximum of 560 mg) ONCE daily. [4, 8, 11]
- No dose increases should be made without consulting infectious diseases or ChAMP.

Streptococcal and enterococcal endocarditis:

- **All ages**: 1 mg/kg/dose given 8 hourly in combination with other agents.[2, 4]
- Multiple daily dosing of gentamicin is only recommended for directed therapy of confirmed streptococcal and enterococcal endocarditis in discussion with infectious diseases.

Cystic Fibrosis:

- Tobramycin is the aminoglycoside of choice in patients with cystic fibrosis. Refer to the ChAMP tobramycin monograph for further information.

Surgical prophylaxis:

- All patients ≥4 weeks old: IV 5 mg/kg (to a maximum dose of 480 mg) as a single dose given 15 to 60 minutes before surgical incision.[11]

Refer to ChAMP surgical prophylaxis guidelines for specific recommendations.

Renal impairment:

- eGFR calculator
- Where possible, consider using a less nephrotoxic agent.
- Dosage adjustment may be required in cases of impaired renal function (with eGFR of less than 60 mL/min/1.73 m^2).[3, 6]
- All patients with renal impairment should have monitoring based on AUC. See monitoring section for further information.
- In cases where gentamicin is required, suggested initial dosing intervals are stated below. All future doses and intervals are to be determined based on therapeutic drug monitoring.
    - eGFR ≥ 60 mL/minute/1.73 m^2: 24 hourly dosing interval
    - eGFR ≥ 40 to <60 mL/minute/1.73 m^2: 36 hourly dosing interval
    - eGFR ≥ 20 to <40 mL/minute/1.73 m^2: 48 hourly dosing interval[3, 6]
    - eGFR <20 mL/minute/1.73m^2: consider alternative agents. If essential, give a single initial dose then contact Pharmacy for advice on monitoring and further doses.[3, 6]

Hepatic impairment:

- No dosage adjustment is required as gentamicin does not undergo hepatic metabolism.[3, 6]

ADMINISTRATION

IV Injection:

- The dose may be given undiluted or diluted to a suitable final volume (up to 20 mL) with compatible fluid and administered over 3 to 5 minutes.[10]
- IV injection is the preferred method of administration for critically unwell patients.

IV infusion:

- Dilute to a suitable volume (e.g. 10 mg/mL or to a final volume of 100 mL) with compatible fluid to allow infusion over 30 to 60 minutes.[4, 5, 10, 12]

IM injection:

- If IV access is not available, gentamicin may be given undiluted by IM injection into a large muscle mass. However, the IV route is preferred for patients with suspected shock or sepsis.[3, 4, 10, 12]
- IM injection is NOT suitable for premature neonates.[4]
- Refer to Intramuscular (IM) injections for further information.

COMPATIBILITY

Compatible fluids:

- Sodium chloride 0.9%
- Glucose 5%
- Glucose 10%
- Hartmann's[10, 12]

Compatible at Y-site:

Compatibilities of IV drugs must be checked when two or more drugs are given concurrently.

MONITORING

Therapeutic drug monitoring:

Monitoring in Neonates:

- Please refer to Neonatal Medication Protocols

Monitoring for patients with normal pharmacokinetics:

- Trough level should be taken immediately prior to the 4th dose in conjunction with a serum creatinine level and should be below the limit of detection (<0.6 mg/L).[1, 3, 5, 6, 8, 11]
- If the trough level is greater than or equal to 0.6 mg/L, contact Pharmacy for advice as this indicates reduced clearance of gentamicin and cessation or dose adjustment is required.
- Follow-up levels should be performed twice weekly unless the clinical situation dictates otherwise (e.g. development of impaired renal function or concurrent use of nephrotoxic drugs where levels should be collected more frequently).[8]

Patients with altered pharmacokinetics:

- Includes patients with Cystic fibrosis (CF), oncology patients, patients with severe burns, trauma patients or patients with impaired renal function.
- These patients should have therapeutic drug monitoring completed with the **FIRST** or **SECOND** dose of gentamicin.
- Monitoring should be based on calculating the drug concentration in the body relative to time, monitoring area under the curve (AUC).
- AUC measurement involves a mathematical calculation that requires the recording of the drug concentration at two specific times.
- Refer to the form MR860.91 Gentamicin and Tobramycin AUC Reporting Form for the specific times required.
- This form should be kept in the patients' notes on the ward and it will be collected and interpreted by the ward pharmacist who will then calculate the AUC.
- The target AUC for Oncology patients is 60-80 mg/L.hr
- **ALL** patients (including those on Hospital in the HOME (HiTH)) require ongoing monitoring of their gentamicin AUC levels at a minimum of once weekly AND/OR following any dose adjustment.

HiTH patients (excluding those with altered pharmacokinetics):

- Require weekly monitoring of their trough levels and renal function monitoring.
- Trough levels should remain below the limit of detection (< 0.6 mg/L).
- If the trough level is greater than or equal to 0.6 mg/L, contact Pharmacy for advice as this indicates reduced clearance of gentamicin and cessation or dose adjustment is required.[1, 3, 5, 8, 11]

Process of therapeutic drug monitoring:

- Blood samples for therapeutic drug monitoring (TDM) for gentamicin may be collected by a capillary blood sample OR by accessing a central venous access device (CVAD) line.
- A capillary blood sample (i.e. finger prick or heel prick for infants <6 months) should be used if there is no CVAD in-situ.
- For patients with a CVAD in-situ the following process should be used:[13]
    - Stop all fluids running through the CVAD line.
    - Flush the line with sodium chloride 0.9%. The volume used is three times the internal line-filling volume of the CVAD device (as per table below).
    - Collect an initial blood sample to be **discarded.** The volume taken is three times the internal line-filling volume of the CVAD device PLUS the additional volume of the IV tubing, injection caps and connectors (as per table below). This is to ensure there is no residue gentamicin in the line which may falsely elevate levels.
    - Collect a **therapeutic drug level monitoring sample** of blood to send to PathWest for determination of the AUC.
    - Administer another flush of sodium chloride 0.9% (volume as per table below) to ensure line does not clot after blood sample is taken.
    - Recommence fluids if required

Line type	Approximate internal fill volume of CVAD and line	Flush and discard volume
Peripherally-Inserted Central Catheter (PICC) and Non-tunnelled Central Venous Catheter (CVC)	1 mL	3 mL
Tunnelled line (broviac) and Implanted (port)	2 mL	6 mL

Collection tube:

- **Paediatric –** Serum, no gel (RED), Lithium heparin, no gel (DRGNLITH) or Lithium heparin-PST (GREEN) [14]

- **Minimum volume required:** 300 microlitres[14]

For further information, refer to the PathWest test directory.

Additional monitoring:

- Ensure adequate hydration is given throughout therapy.[2, 12]
- Renal function and electrolytes monitoring should be performed at baseline and at least twice weekly whilst on treatment.[1, 3, 4, 6]
- Patients receiving treatment > 2 weeks with gentamicin must be monitored for hearing loss and vestibular toxicity every 1 to 2 weeks.[3, 4]

ADVERSE EFFECTS

Common: Nephrotoxicity (usually reversible but can be anticipated if treatment extends beyond 7-10 days, or if pre-existing renal impairment). Clinically evident vestibular ototoxicity (nausea, vomiting, vertigo, nystagmus, difficulties with gait) and cochlear ototoxicity (noticeable hearing loss, tinnitus, a feeling of fullness in ear) occur in 2–4% of patients. Ototoxicity may be delayed in onset and may be irreversible.[2, 8]

Infrequent: increased risk of infection, skin reactions, cough.[8]

Rare: Anaphylaxis, bronchospasm, oliguria, peripheral neuropathy and neuromuscular blockade, electrolyte disturbances (e.g. hypomagnesaemia), anaemia, azotaemia, eosinophilia, fever, headache, paraesthesia, altered taste, aphonia, chest discomfort, diarrhoea, haemoptysis.[2, 8]

STORAGE

Ampoule should be protected from light and stored below 25˚C.[5, 10]

INTERACTIONS

This medication may interact with other medications; consult PCH approved references (e.g. Clinical Pharmacology), a clinical pharmacist or PCH Medicines Information Service on extension 63546 for more information.

Please note: The information contained in this guideline is to assist with the preparation and administration of **gentamicin (intravenous)**. Any variations to the doses recommended should be clarified with the prescriber prior to administration

Related CAHS internal policies, procedures and guidelines

Children's Antimicrobial Management Program (ChAMP) Policy

ChAMP Guidelines and Monographs
KEMH Neonatal Medication Protocols

References

1. Royal Australian College of General Practitioners, Pharmaceutical Society of Australia, Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists. AMH: Children's Dosing Companion. Adelaide: Australian Medicines Handbook Pty Ltd; 2022.
2. Australian Medicines Handbook. Adelaide, S. Aust.: Australian Medicines Handbook; 2025 [cited 2025 12th June]. Available from: https://amhonline-amh-net-au.pklibresources.health.wa.gov.au/.
3. Up To Date - Paediatric Drug information [Internet]. Lexicomp. 2025 [cited 2025 June 12th]. Available from: https://www-uptodate-com.pklibresources.health.wa.gov.au/contents/table-of-contents/drug-information/pediatric-drug-information.
4. Clinical Pharmacology powered by ClinicalKey [Internet]. Elsvier. 2025 [cited 2025 June 12th]. Available from: https://www-clinicalkey-com.pklibresources.health.wa.gov.au/pharmacology/.
5. Electronic Medicines Compendium (emc). Surrey: DataPharm Ltd; 2024.
6. IBM Micromedex [Internet]. Truven Health Analytics. 2025 [cited 2025 June12th]. Available from: http://www-micromedexsolutions-com.pklibresources.health.wa.gov.au/micromedex2/librarian.
7. Phelps S HT, Lee K ,. Pediatric Injectable Drugs: The Teddy Bear Book. Maryland: American Society of Health-System Pharmacists.
8. Paediatric Formulary Committee. BNF for Children: 2025. London: BMJ Group Pharmaceutical Press; 2025.
9. MIMS Australia. MIMS online [full product information]. St Leonards, N.S.W: CMP Medica Australia.; 2023 [cited 2023 31th October].
10. Symons K. Wong Ee. Australian injectable drugs handbook. Abbotsford: The Society of Hospital Pharmacists of Australia; 2023.
11. Antibiotic Writing Group. Therapeutic Guidelines - Antibiotic. West Melbourne: Therapeutic Guidelines Ltd; 2025. Available from: https://tgldcdp-tg-org-au.pklibresources.health.wa.gov.au/etgAccess.
12. Paediatric Injectable Guidelines 9th Ed [Internet]. Royal Children's Hospital 2024.
13. Lichliter RL, Tremewan LE, Shonka NM, Mehnert JE, Brennan L, Thrasher JM, et al. Therapeutic antibiotic serum concentrations by two blood collection methods within the pediatric patient: A comparative effectiveness trial. J Spec Pediatr Nurs. 2018;23(2):e12212.
14. PathWest. PathWest - test directory Perth2025 [cited 2025. Available from: https://pathwesttd.health.wa.gov.au/testdirectory/.

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