MONOGRAPH

Amikacin 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.[1-4]

Amikacin is a High Risk Medicine.

INDICATIONS AND RESTRICTIONS

Amikacin is indicated in the treatment of serious gram-negative infection that are resistant to other aminoglycosides. It is also used in the treatment of resistant non-tuberculosis *Mycobacterium* species.[3, 5]

IV: Protected (red) Antibiotic

ChAMP approval is required prior to prescription.

CONTRAINDICATIONS

- Hypersensitivity to amikacin or any component of the formulation.[2-4, 6]
- Amikacin is contraindicated in patients with a history of vestibular or auditory toxicity caused by an aminoglycoside.[5]
- Amikacin is contraindicated in patients with myasthenia gravis due to the risk of impaired neuromuscular transmission.[7-9]

PRECAUTIONS

- Amikacin should be used with caution in patients with a known allergy to other aminoglycosides due to the risk of cross-reactivity.[4, 7, 9]
- The injection contains sodium metabisulfite which may cause allergic reactions in susceptible people.[4, 10]
- Amikacin should be used with caution in patients with neuromuscular disease due to the increased risk of muscle weakness and respiratory depression.[2, 4]
- Patients with hypocalcaemia, hypermagnesemia, co-administration with general anaesthesia or large transfusions of citrated blood increases the risk of neuromuscular adverse effects, including in people with normal neuromuscular function.[2]
- Amikacin should be used with caution in patients with renal impairment and/or dehydration due to the risks of further ototoxicity and nephrotoxicity.[8, 9]
- Amikacin should be used with caution in patients with a first degree relative who has experienced aminoglycoside induced auditory toxicity or who has a genomic variant in MT-RNRI as they may be at increased risk of aminoglycoside induced toxicity.[4, 5]

FORMULATIONS

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

- 500 mg/2 mL solution for injection vial

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates: Refer to Neonatal Medication Protocols

IV / IM - Children ≥ 4 weeks:

- **General once daily dosing:** 20 mg/kg/dose (to a maximum of 1.5 grams) ONCE daily.[5]
- **Patients with cystic fibrosis, critical illness, malignancy or severe burn injury:** 30 mg/kg/dose (to a maximum of 1.5 grams) ONCE daily.[3, 4]
- **Non- tuberculosis mycobacterial infections:** 15 mg/kg/dose (to a maximum of 1.5 grams) given ONCE daily.[2, 4] Intermittent dosing may be considered in adolescents in discussion with infectious diseases.[2, 4, 11]

Dosing in Overweight and Obese Children: Dose based on adjusted body weight.[1, 3, 4, 12, 13]

Renal impairment:

eGFR calculator

- Where possible, consider using a less nephrotoxic agent.
- Trough levels should be collected and reviewed prior to any subsequent doses to avoid toxicity See monitoring section.

Where amikacin is required, *initial* suggested dosing intervals are:

eGFR	Initial dosing interval[4]
≥ 60 mL/minute/1.73m^2	24 hourly
≥ 40 to < 60 mL/minute/1.73m^2	36 hourly dosing interval with monitoring prior to any further doses
≥ 20 to < 40 mL/minute/1.73m^2	48 hourly dosing interval with monitoring prior to any further doses
< 20 mL/minute/1.73m^2	If essential, give a single dose and monitor for clearance before any further doses are administered. Contact infectious diseases for advice on alternative agents.

Hepatic impairment:

- No dose adjustments required.[4]

ADMINISTRATION

IV infusion:

- Dilute to a final concentration of 10 mg/mL or less with a compatible fluid. Infuse over 30 to 60 minutes for children. For infants a longer infusion time of 1 to 2 hours is recommended.[3, 6, 8, 10, 14]
- Use the solution prepared in Pharmacy Compounding Service (PCS) where possible.

IM injection:

- If IV access is not available this medication may be given undiluted by IM injection.[3, 10, 14] Refer to PCH guideline Intramuscular (IM) Injections (internal link).

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids:

- Sodium chloride 0.45% and 0.9%
- Glucose 5% and 10%
- Sodium chloride / glucose solutions
- Hartmann's
- Ringer's[3, 10, 14]

Compatible at Y-site:

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

MONITORING

Therapeutic drug monitoring:

- Trough level paired with creatinine should be taken immediately prior to the 4th dose and should be less than 5 mg/L.[4, 8]
- If the trough level is greater than 5 mg/L, contact Infectious Disease or ChAMP for advice as this indicates reduced clearance of amikacin and dose adjustment or cessation is required.[4, 8]

- ALL patients require repeat levels after any dose change and repeat levels should be performed twice weekly with creatinine unless the clinical situation dictates otherwise (e.g. impaired renal function and concurrent use of nephrotoxic drugs where levels should be collected more frequently).[4, 8]

Process of therapeutic drug monitoring:

- Blood samples for therapeutic drug monitoring (TDM) for amikacin may be collected via a capillary blood sample OR via 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[15]:
    - 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 PLUS the additional volume of the IV tubing, injection caps and connectors (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 amikacin 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 trough level.
    - 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 (e.g. Broviac®) and implanted (port)	2 mL	6 mL

Collection tube:

- Paediatric - Lithium Heparin PST (GREEN)1 mL or Lithium Heparin, No Gel (DKGNLITH) 1 mL or Serum no gel (RED)

Minimum volume required – 1 mL whole blood.[16]

For further information, refer to the PathWest test directory.

Neonates:

Please refer to neonatal clinical care drug protocols

Additional monitoring:

- Renal function and electrolytes should be performed twice weekly whilst on treatment.[3, 4, 9]

- Patients receiving prolonged treatment with amikacin (greater than 72 hours) must be monitored for hearing loss and vestibular toxicity every 1 to 2 weeks.[2, 3] Pre-treatment audiology is recommended for all patients on amikacin with treatment to continue beyond 10 days.[4, 6, 9]

ADVERSE EFFECTS

Common: Dysphonia, nephrotoxicity (usually reversible but often occurs in treatment extending longer than 7 to 10 days), vestibular (nausea, vomiting, vertigo, nystagmus) and cochlear (hearing loss, tinnitus) ototoxicity.[2, 8]

Infrequent: cough, skin reactions.[8]

Rare: Anaphylaxis, albuminuria, arthralgia, hypotension, bronchospasm, oliguria, peripheral neuropathy, muscle twitching, tremor, neuromuscular blockade.[2, 8]

STORAGE

- 500 mg/2 mL vial should be stored below 25˚C.[7, 10]
- Products prepared by PCS should be stored between 2˚C and 8˚C[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 **amikacin**. Any variations to the doses recommended should be clarified with the prescriber prior to administration

Related CAHS internal policies, procedures and guidelines

Antimicrobial Stewardship

ChAMP Empiric Guidelines and Monographs

KEMH Neonatal Medication Protocols

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