according to serum-amikacin concentration; maximum 15 g per course

DOSES AT EXTREMES OF BODY-WEIGHT

- To avoid excessive dosage in obese patients, use ideal weight for height to calculate dose and monitor serum-amikacin concentration closely

- **UNLICENSED USE**
- With intravenous use Dose for cystic fibrosis not licensed.
- **INTERACTIONS** → Appendix 1: aminoglycosides
- **SIDE-EFFECTS**
- **Uncommon** Superinfection
- **Rare or very rare** Albuminuria · arthralgia · balance impaired · hypotension · muscle twitching · tremor
- **Frequency not known** Apnoea · neuromuscular blockade · paralysis
- **MONITORING REQUIREMENTS**
- With intravenous use *Multiple daily dose regimen*: one-hour ('peak') serum concentration should not exceed 30 mg/litre; pre-dose ('trough') concentration should be less than 10 mg/litre. *Once daily dose regimen*: pre-dose ('trough') concentration should be less than 5 mg/litre.
- **DIRECTIONS FOR ADMINISTRATION**
- With intravenous use For *intravenous infusion*, dilute with Glucose 5% *or* Sodium Chloride 0.9%; give over 30–60 minutes.
- **PRESCRIBING AND DISPENSING INFORMATION** Local guidelines may vary in the dosing advice provided.

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug. Forms available from special-order manufacturers include: solution for injection

Solution for injection

- **Amikacin (Non-proprietary)**
  Amikacin (as Amikacin sulfate) 250 mg per 1 ml Amikacin 500mg/2ml solution for injection vials | 5 vial PoM £60.00 (Hospital only)
- **Amikin** (Vianex S.A.)
  Amikacin (as Amikacin sulfate) 50 mg per 1 ml Amikin 100mg/2ml solution for injection vials | 5 vial PoM £10.33

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Gentamicin

19-Mar-2020

- **INDICATIONS AND DOSE**

Septicaemia | Meningitis and other CNS infections | Biliary-tract infection | Endocarditis | Pneumonia in hospital patients | Adjunct in listerial meningitis

- BY INTRAVENOUS INFUSION
- Child: Initially 7 mg/kg, to be given in a once daily regimen (not suitable for endocarditis or meningitis), subsequent doses adjusted according to serum-gentamicin concentration
- BY INTRAMUSCULAR INJECTION, OR BY SLOW INTRAVENOUS INJECTION
- Child 1 month-11 years: 2.5 mg/kg every 8 hours, to be given in a multiple daily dose regimen, intravenous injection to be administered over at least 3 minutes
- Child 12-17 years: 2 mg/kg every 8 hours, to be given in a multiple daily dose regimen, intravenous injection to be administered over at least 3 minutes

Neonatal sepsis

- BY SLOW INTRAVENOUS INJECTION, OR BY INTRAVENOUS INFUSION
- Neonate up to 7 days: 5 mg/kg every 36 hours, to be given in an extended interval dose regimen.
- Neonate 7 days to 28 days: 5 mg/kg every 24 hours, to be given in an extended interval dose regimen.

Pseudomonal lung infection in cystic fibrosis

- BY SLOW INTRAVENOUS INJECTION, OR BY INTRAVENOUS INFUSION
- Child: 3 mg/kg every 8 hours, to be given in a multiple daily dose regimen, intravenous injection to be administered over at least 3 minutes

Bacterial ventriculitis and CNS infection (supplement to systemic therapy) (administered on expert advice)

- BY INTRATHECAL INJECTION, OR BY INTRAVENTRICULAR INJECTION
- Neonate: (consult local protocol).
- Child: Initially 1 mg daily, then increased if necessary to 5 mg daily, seek specialist advice

Acute pyelonephritis (once daily dose regimen) | Urinary tract infection (catheter-associated, once daily dose regimen)

- BY INTRAVENOUS INFUSION
- Child 3 months-15 years: Initially 7 mg/kg once daily, subsequent doses adjusted according to serum-gentamicin concentration
- Child 16-17 years: Initially 5–7 mg/kg once daily, subsequent doses adjusted according to serum-gentamicin concentration

DOSES AT EXTREMES OF BODY-WEIGHT

- With intramuscular use or intravenous use To avoid excessive dosage in obese patients, use ideal weight for height to calculate parenteral dose and monitor serum-gentamicin concentration closely.

- **UNLICENSED USE** Gentamicin doses in BNF publications may differ from those in product literature.

IMPORTANT SAFETY INFORMATION

MHRA/CHM ADVICE: POTENTIAL FOR HISTAMINE-RELATED ADVERSE DRUG REACTIONS WITH SOME BATCHES (NOVEMBER 2017)

- With intramuscular use or intrathecal use or intravenous use Following reports that some batches of gentamicin sulphate active pharmaceutical ingredient (API) used to manufacture gentamicin may contain higher than expected levels of histamine, which is a residual from the manufacturing process, the MHRA advise to monitor patients for signs of histamine-related adverse reactions; particular caution is required in patients taking concomitant drugs known to cause histamine release, in children, and in patients with severe renal impairment.

- **INTERACTIONS** → Appendix 1: aminoglycosides
- **SIDE-EFFECTS** Antibiotic associated colitis · blood disorder · depression · encephalopathy · hallucination · hepatic reaction · neurotoxicity · peripheral neuropathy · seizure · stomatitis · vestibular damage
- **MONITORING REQUIREMENTS**
- With intravenous use in neonates Extended interval dose regimen in neonates: pre-dose ('trough') concentration should be less than 2 mg/litre (less than 1 mg/litre if more than 3 doses administered); consider monitoring one hour ('peak') concentration in neonates with poor response to treatment, with oedema, with Gram-negative infection, or with birth-weight greater than 4.5 kg (consider increasing dose if 'peak' concentration less than 8 mg/litre in severe sepsis).
- With intravenous use Once daily dose regimen: pre-dose ('trough') concentration should be less than 1 mg/litre.
- With intramuscular use or intravenous use Multiple daily dose regimen: one hour ('peak') serum concentration should be 5–10 mg/litre; pre-dose ('trough') concentration should be less than 2 mg/litre. Multiple daily dose regimen for endocarditis: one hour ('peak') serum concentration should be 3–5 mg/litre; pre-dose ('trough') concentration should be less than 1 mg/litre. Serum-gentamicin