All Wales Neonatal Unit Gentamicin IV Drug Monograph

FORM

Ampoules containing 20mg in 2mL gentamicin in solution. This is the **paediatric** injection strength.
Ampoules containing 80mg in 2mL gentamicin in solution.

INDICATIONS

Empirical treatment for early/late onset neonatal infection, in combination with other antibiotics, please see local guidelines.
Treatment of meningitis (GBS, Listeria).
Treatment of necrotising enterocolitis (NEC).

DOSE

Note: In very immature infants (≤ 28 weeks gestation), an individualised treatment strategy may be followed by measuring the serum gentamicin level 22 hours after a single dose of 5mg/kg. Please see Neonatal Formulary for further information.

Age	Dose	Initial Dosing Interval	Route
< 7 days	5mg/kg	Every 36 hours	Slow IV bolus over 3-5 minutes
7 – 28 days	5mg/kg	Every 24 hours	
> 28 days	Consider 7mg/kg	Every 24 hours	IV infusion

Review the clinical need for gentamicin daily.
Where possible, parenteral treatment duration should not exceed 7 days.

Use with caution in renal impairment – increased risk of adverse drug reactions (such as nephrotoxicity and irreversible ototoxicity) due to prolonged high gentamicin levels.

Monitor for signs of renal impairment:

- Poor urine output (or anuria)
- Increase in creatinine
- Increased serum urea

PRESCRIBING

Please refer to local prescribing guidelines for further information on how gentamicin should be prescribed on the medication chart and whether stickers/dedicated medication charts are in use.

PREPARATION
Before preparing and administering gentamicin double check strength as more than one preparation is available.

Reconstitution and dilution
20mg/2mL strength: Already in solution.
No further dilution required for IV bolus injection. Give gentamicin and subsequent sodium chloride 0.9% flush over 3-5 minutes.
For IV infusion, dilute to a concentration of 2mg/mL with sodium chloride 0.9% or glucose 5% and give required dose over 60 minutes using an infusion pump.

80mg/2mL strength:

1. Take 0.5mL (20mg) of gentamicin 80mg/2mL injection
2. Dilute with 1.5mL of either 5% glucose or 0.9% sodium chloride
3. This gives a concentration of 20mg/2mL

No further dilution required for IV bolus injection. Give gentamicin and subsequent sodium chloride 0.9% flush over 3-5 minutes.
For IV infusion, dilute to a concentration of 2mg/mL with sodium chloride 0.9% or glucose 5% and give required dose over 60 minutes using an infusion pump.

Flushing
NOTE: Flush well before and after dose if the same line is being used for penicillins or cephalosporins. Separate administration sites for these antibiotics is preferable.

Compatibilities and Incompatibilities (This table is not exhaustive, contact pharmacy for further information)

Solution compatibility	Sodium chloride 0.45%, sodium chloride 0.9%, glucose 5%, glucose 10%
Solution incompatibility	Sodium bicarbonate
IV line compatibility **(Please note: although not incompatible with these medications, the administration of gentamicin should not facilitate bolusing of other medication e.g. inotropes)**	Caffeine citrate, dopamine (used in practice, no clinical data), fluconazole, magnesium sulfate, metronidazole, midazolam, milrinone, morphine, vecuronium.
IV line incompatibility	Penicillins (e.g. flucloxacillin), cephalosporins (e.g. cefotaxime), furosemide, heparin, aciclovir
Notes	If gentamicin and flucloxacillin are being administered at the same time, a sodium chloride 0.9% flush can be used to separate the two drugs in the administration line. Care must be taken not to fluid overload the infant with the volume of flushes used.

MONITORING

GENTAMICIN LEVELS

Pre dose (trough) levels	When should I take the first trough level?	A plasma pre-dose **(trough)** level should be taken immediately before or up to 6 hours prior to the 2nd dose.	
	Should I wait for the results before giving the second dose?	**No**, unless there is suspicion of or known renal dysfunction (oliguria/anuria/raised creatinine). **Review the result before giving the third dose.**	
	What are the target trough levels?	<28 days old	First pre-dose (trough) level: **<2mg/L**
			Subsequent pre-dose (trough) levels (once >3 doses administered: **<1mg/L**
		>28 days old	**<1mg/L**
	When should trough levels be repeated?	Every 3rd dose or more frequently if the dose has been changed, renal impairment is present or the patient is unstable.	
	Should I wait for the results before giving subsequent doses?	**No**, unless there is suspicion of or known renal dysfunction (oliguria/anuria/raised creatinine). **Review the result before giving any further doses.**	
Post dose (peak) levels	When are post-dose (peak) levels required?	Peak levels are **hardly ever required**. Consider in selected babies: • Unsatisfactory response to treatment • Oedema • Macrosomia (birth weight more than 4.5kg) • Gram-negative infection • Staphylococcal infection Measure peak concentrations 1 hour after gentamicin administration, if given by bolus or infusion.	
	What is the target post-dose (peak) level?	8-12mg/L	

Blood sample

- 0.5mL clotted capillary sample.
- Do not use **any** lumen in which gentamicin has ever been administered in order to prevent falsely high gentamicin pre-dose (trough) levels.
- Record the time the level was taken and the time of the last gentamicin dose on the request form.

When interpreting gentamicin levels it is important to determine if the infant received all doses and that the blood sample was taken at the correct time. Any result from a sample taken at the incorrect time should be ignored and a level should be retaken at the correct time.

Neonates <28 days old		
Gentamicin Level		**Action**
Pre dose (trough) level	First pre-dose (trough) level <2mg/L:	Give 3rd dose and continue with current dosage interval.
	First pre-dose (trough) level ≥ 2mg/L:	• Extend dosage interval by 12 hours. • Discuss with microbiology whether alternative antibiotic therapy is necessary. • Repeat pre-dose (trough) level immediately before or up to 6 hours prior to the 3rd dose. • Wait for the level before giving the 3rd dose. • If this level <2mg/L administer the 3rd dose and continue further doses. • If this level ≥2mg/L continue extending dosage interval by 12 hours i.e. from 36 to 48 hourly and recheck pre-dose (trough) level before each subsequent dose is due.
	Pre-dose (trough) level < 1mg/L when > 3 doses administered	Give dose and continue with current dosage interval.
	Pre-dose (trough) level ≥ 1mg/L when > 3 doses administered	• Extend dosage interval by 12 hours. • Discuss with microbiology whether alternative antibiotic therapy is necessary. • Repeat pre-dose (trough) level immediately before or up to 6 hours prior to the next dose. • Wait for the level before giving the dose. • If level <1mg/L administer the dose. • If this level ≥ 1mg/L continue extending dosage interval by 12 hours i.e. from 36 to 48 hourly and recheck pre-dose (trough) level before each subsequent dose is due.
Post dose (peak) level	Post-dose (peak) level < 8mg/L in Gram negative or Staphylococcal infection	Consider increasing dose.

Babies >28 days old		
Gentamicin Level		**Action**
Pre dose (trough) level	Pre-dose (trough) level < 1mg/L	Give dose and continue with current dosage interval.
	Pre-dose (trough) level ≥ 1mg/L	• Extend dosage interval by 12 hours. • Discuss with microbiology whether alternative antibiotic therapy is necessary. • Repeat pre-dose (trough) level immediately before or up to 6 hours prior to the next dose. • Wait for the level before giving the dose. • If level <1mg/L administer the dose. • If this level ≥ 1mg/L continue extending dosage interval by 12 hours i.e. from 36 to 48 hourly and recheck pre-dose (trough) level before each subsequent dose is due.
Post dose (peak) level	Post-dose (peak) level < 8mg/L in Gram negative or Staphylococcal infection	Consider increasing dose.

OTHER MONITORING

For more information including CAUTIONS, CONTRA-INDICATIONS, INTERACTIONS and SIDE-EFFECTS, please see BNFc (online or app is most up to date) or summary of product characteristics (SPC). For more information on ADMINISTRATION, see NHS Injectable Medicines Guide.

FURTHER INFORMATION/ADDITIONAL CONSIDERATIONS

NPSA Patient Safety Alert Safer Use of Gentamicin for Neonates Feb 2010

MHRA/CHM advice: Aminoglycosides (gentamicin, amikacin, tobramycin, and neomycin): increased risk of deafness in patients with mitochondrial mutations January 2021

KEY REFERENCES

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