

# **TOBRAMYCIN**

Read in conjunction with **Disclaimer** 



## HIGH RISK Medication 🛕



<u>Formulary: Restricted</u> Requires Neonatologist or Microbiologist review within 24 hours of initiation.					
Presentation	Vial: 80 mg/2 mL				
Classification	Aminoglycoside	e antibiotic			
Indication	Effective again		ative organisms, wito gentamicin.	th superior anti-	
Special Considerations	<ul> <li>Contraindicated in patients with hypersensitivity to tobramycin, other aminoglycosides or any component of the formulation.</li> <li>Caution in patients with pre-existing renal impairment, auditory or vestibular impairment, hypocalcaemia, depressed neuromuscular transmission.</li> </ul>				
Monitoring	<ul> <li>Urine output</li> </ul>	peutic Drug Monitor at. nitrogen and creat			
	<ul> <li>Monitoring for IV and IM dosing only:</li> <li>Trough level: 0.4 mL blood immediately prior to dose.</li> <li>Peak level: 0.4 mL blood 1 hour after dose infusion complete.</li> <li>Dose First level due Second level Subsequent</li> </ul>				
	frequency	with	due with	levels	
	24 hourly	4 <sup>th</sup> dose (day 4)	8 <sup>th</sup> dose (day 8)	Every 4 days	
	48 hourly	3 <sup>rd</sup> dose (day 5)	5 <sup>th</sup> dose (day 9)	Every 4 days	
Therapeutic Drug Monitoring	<ul> <li>Additional levels required:</li> <li>After a dose change take a trough and peak blood sample with the second adjusted dose.</li> <li>If an infant's clinical situation (i.e. renal failure) is likely to lead to unpredictable levels take more frequent levels.</li> </ul> Expected levels:				
	<ul> <li>Trough level at 24 hours post dose: less than 2 mg/L</li> <li>Trough level at 48 hours post dose: less than 1 mg/L</li> <li>Peak: greater than 10 mg/L</li> </ul>				
	<ul> <li>Area Under the Curve (AUC):</li> <li>Calculated using the trough and peak levels</li> <li>Ideal AUC range: 80 to 100 mg/L.hour</li> <li>Calculated using Neogent (Gentamicin Dosage Calculator) available on the KEMH Neonatal Medication Protocols page (Intranet access only). The target AUC level for tobramycin is the same as for gentamicin.</li> <li>Follow recommendations given by Neogent calculator for dose adjustment.</li> </ul>				

Compatibility	Fluids: Sodium chloride 0.9%, glucose 5%, glucose 10%				
Incompatibility	IV aminoglycoside antibiotics, including tobramycin and gentamicin, are <b>inactivated</b> by IV cephalosporins, penicillins and teicoplanin. Ensure lines are adequately flushed between antibiotics or administer at different times.				
Interactions	<ul> <li>Increased risk of nephrotoxicity when administered with other nephrotoxic drugs and cephalosporins.</li> <li>Aminoglycosides may enhance the respiratory depressant effect of neuromuscular-blocking agents (e.g. vecuronium) and may prolong blockade.</li> </ul>				
Side Effects	Renal: Increased blood urea nitrogen, increased serum creatinine, oliguria, nephrotoxicity.  Ototoxicity: Auditory and vestibular impairment, hearing loss. Endocrine: Decreased serum calcium, magnesium, potassium and sodium.  Dermatologic: Dermatitis, rash, urticarial. Central nervous system: Lethargy. Haematologic: Anaemia, leucocytosis, leukocytopenia, thrombocytopenia. Gastrointestinal: Diarrhoea, vomiting. Local: Pain at injection site.				
Storage & Stability	Vial (Pfizer® preservative free): Refrigerate at 2 to 8°C, do not freeze. Protect from light.  Vial (Viatris®): Store at room temperature, below 25°C. Protect from light.  Other brands: Follow storage instructions on product information.				
Comments	Preservative and sulfite free tobramycin should be used for neonates, if available.				

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Dosage

**Preparation** 

Administration

## Presentation Vial: 80 mg/2 mL

Available from CIVAS (KEMH Only): 10 mg/mL



Corrected Gestational Age	Postnatal Age	Dose	Frequency		
Less than 30	0 to 7 days	5 mg/kg	Every 48 hours		
weeks	Greater than 7 days	5 mg/kg	Every 24 hours		
30 to 35 weeks	0 to 7 days	6 mg/kg	Every 48 hours		
	Greater than 7 days	6 mg/kg	Every 24 hours		
Greater than	0 to 14 days	4.5 mg/kg	Every 24 hours		
35 weeks	Greater than 14 days	7 mg/kg	Every 24 hours		
Dose adjustment					
See Therapeutic Drug Monitoring.					
<ul> <li>Renal impairment: Use with caution. Contact microbiologist/ID for advice.</li> </ul>					
Withdraw 2 mL (80 mg) of tobramycin and add 6 mL of					

compatible diluent to make a final volume of 8 mL.

Infuse via syringe driver pump over 20 to 60 minutes.

IV push (only to be used if IV infusion not possible):

Concentration now equal to 10 mg/mL.

IV infusion (preferred option):

Inject over 10 minutes.

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30 to 35 weeks	0 to 7 days	6 mg/kg	Every 48 hours
	Greater than 7 days	6 mg/kg	Every 24 hours
Greater than 35 weeks	0 to 14 days	4.5 mg/kg	Every 24 hours
	Greater than 14 days	7 mg/kg	Every 24 hours

### Dose adjustment

- Intramuscular (IM) injection is associated with variable absorption, especially in a very small infant.
- See Therapeutic Drug Monitoring.
- Renal impairment: Use with caution. Contact microbiologist/ID for advice.

**Preparation** Use undiluted.

**Administration** 

Dosage

- Draw up the prescribed dose.
- Inject as per the Medication Administration Guideline.

	Presentation	Vial: 80 mg/2 mL	
7	Dosage	20 mg every 12 hours	
OIL	Preparation	Dilute required dose to 3 mL (or an appropriate volume) with sodium chloride 0.9%	
NEBULISATION	Administration	<ul> <li>Nebulise via endotracheal tube</li> <li>The expiratory block of ventilators should be changed on a weekly basis when nebulised drugs are used</li> </ul>	
NEBI	Comments	<ul> <li>There is no evidence to support the use of nebulised tobramycin for the eradication of endotracheal tube colonisation.</li> <li>Therapeutic drug monitoring may be required. Contact microbiology/ID for advice.</li> </ul>	

#### Related Policies, Procedures, and Guidelines

**HDWA Mandatory Policies:** 

MP 0131/20: WA High Risk Medication Policy

**Clinical Practice Guidelines:** 

CAHS Neonatology - Sepsis

**Pharmaceutical and Medicines Management Guidelines:** 

<u>CAHS Neonatology – Medication Administration Guideline</u>

High Risk Medicines

WNHS Cold Chain Management for Medications and Vaccines

**CAHS Medication Refrigerators and Freezers** 

#### References

Ainsworth SB. Neonatal formulary 7: drug use in pregnancy and the first year of life. Seventh ed. Chichester (West Sussex): John Wiley & Sons Inc.; 2015. 631 p.506

AusDI. Tobramycin PF (Tobramycin Sulfate). In: AusDI By Medical Director [Internet]. Australia: AusDI by Medical Director; 2024 [cited 2024 Aug 12]. Available from: <a href="https://www.ausdi.com/">https://www.ausdi.com/</a>

Australasian Neonatal Medicines Formulary (ANMF). Tobramycin. In: Australasian Neonatal Medicines Formulary [Internet]. Sydney, New South Wales; 2020 [cited 2024 Aug 12]. Available from: <a href="https://www.anmfonline.org">www.anmfonline.org</a>

Committee on Infectious Diseases, American Academy of Pediatrics. David W. Kimberlin, MD, FAAP, ed. 2024. Red Book: 2024-2027 Report of the Committee on Infectious Diseases - 33rd Ed. American Academy of Pediatrics.

Howard-Thompson, A., & Christensen, M. L. (2008). Elevated tobramycin concentrations following endotracheal administration in a premature infant. The journal of pediatric pharmacology and therapeutics: JPPT: the official journal of PPAG, 13(2), 88–92. https://doi.org/10.5863/1551-6776-13.2.88

Lexicomp. Tobramycin (systemic). In: UpToDate [Internet]. Alphen aan den Rijn (Netherlands): Wolters Kluwer; 2024 [cited 2024 Aug 12]. Available from: <a href="https://www.uptodate.com/">https://www.uptodate.com/</a>

Phelps SJ, Hagemann TM, Lee KR, Thompson AJ. Pediatric Injectable Drugs: The Teddy Bear Book. Eleventh ed. Bethesda (Maryland): American Society of Health-System Pharmacists; 2018. p.830-833

Society of Hospital Pharmacists of Australia. Tobramycin. In: Australian Injectable Drugs Handbook [Internet]. St Leonards, New South Wales: Health Communication Network; 2024 [cited 2024 Aug 12]. Available from: <a href="http://aidh.hcn.com.au">http://aidh.hcn.com.au</a>

Truven Health Analytics. Tobramycin. In: NeoFax [Internet]. Greenwood Village (CO): Truven Health Analytics; 2024 [cited 2024 Aug 12]. Available from: <a href="https://www.micromedexsolutions.com/neofax">https://www.micromedexsolutions.com/neofax</a>

## **Document history**

Keywords	Tobramycin, aminoglycoside, sepsis, infection, antibiotic					
Document Owner:	Chief Pharmacist					
Author/ Reviewer	KEMH & PCH Pharmacy/Neonatology Directorate					
Version Info:	V2.0 – full review, new template					
Date First Issued:	10/2013	Last Reviewed:	12/08/2024 Review Date: 12/08/2029			12/08/2029
Endorsed by:	Neonatal Directorate Management Group Date: 07/10/2024					
NSQHS Standards Applicable:	Std 1: Clinical Governance Std 4: Medication Safety				ety	
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