






MEDICATION SAFETY COMMUNIQUÉ

Subject:	Gentamicin 80mg/2mL (Pfizer) Preservative free ampoules – supply disruption		
Purpose:	Information		
Issued by:	Pharmacy Department	Issue Date:	12 th of November 2024
Approved by:	Leith Lilley, Acting Director Pharmacy, QCH Dr Julia Clark, Director, Infection Management and Prevention Service, QCH		
Issue and Impact within CHQ:	There is currently a disruption to supply of gentamicin (Pfizer) 80mg/2mL (as sulfate) injection BP ampoules which are expected to continue until 31 March 2025 . The alternative TGA registered/S19A products are gentamicin 80 mg/2mL (as sulfate) solution for injection ampoule is Noridem or Hexal SF .		
Target Audience:	Action Required:		
All CHQ Staff	<p>Gentamicin is a widely used aminoglycoside antibiotic listed on the QH Medicines Formulary, primarily used for short term empiric treatment of gram-negative infections or surgical prophylaxis in accordance with local antimicrobial policies.</p> <p>Review stock holdings of Pfizer gentamicin product and develop a plan to changeover to the Noridem or Hexal SF brand. It is recommended to not use different presentations concurrently to avoid confusion.</p> <ul style="list-style-type: none">• Review and consider allergy status prior to prescribing or administering Noridem (sodium metabisulfite) or Hexal SF (acetylcysteine) Gentamicin.• Be aware that Noridem or Hexal SF gentamicin is not appropriate for administration via inhalation and other off-label routes of administration.• Noridem or Hexal SF gentamicin should be used with caution in extreme premature neonates, where allergy status has not been established.• For those patients where use of the Noridem or Hexal SF product is unsuitable or contraindicated, expert advice should be sought from Infectious Diseases or Microbiology regarding possible alternatives. <p>Refer to Appendix - Important difference between currently available gentamicin injection products.</p>		
Safety Alert	<p>Noridem gentamicin contains sodium metabisulfite as an excipient and is presented in a glass ampoule.</p> <ul style="list-style-type: none">• In patients with sulfite (or sulphite) sensitivity, sodium metabisulfite can cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people.• For more information on sulfite sensitivity, refer to the Australasian Society of Clinical Immunology and Allergy – Sulfite Sensitivity Frequently Asked Questions (FAQ).• Noridem gentamicin should not be administered via inhalation due to the risk of airway irritation associated with the presence of sodium metabisulfite.• Administration via other off-label routes (such as epidural, intrathecal or intraventricular) are also contra-indicated due to the presence of sodium metabisulfite.		
Contact for further information:	If you need assistance with selecting an alternative antibiotic choice, please contact AMS Pharmacist on 0436 815 492. Please contact Pharmacy - Claire George (Clinical Lead – Materials Management) on 07 3068 1945 if you have any questions regarding supply or stock.		



Appendix: Important difference between currently available gentamicin injection products

	Gentamicin (Pfizer) 80 mg/ 2mL ampoule (preservative free) ARTG 11376	Gentamicin (Noridem) 80 mg/ 2mL ampoule ARTG 391250	Gentamicin (Hexal SF) 80 mg/ 2mL S19A
Image			
Presentation	Plastic ampoule	Glass ampoule	Glass ampoule
Excipients	Disodium edetate, water for injections, sodium hydroxide, sulfuric acid	Disodium edetate, sodium metabisulfite, water for injections, sodium hydroxide, sulfuric acid	Acetylcysteine, disodium edetate, sodium hydroxide, water for injections
Language on product	English	English	German
Intravenous use	Suitable (all age groups – including premature neonates) Alternative: Premature neonates - Preservative free Tobramycin 80 mg/ 2mL Term neonates and children up to 18 years, use Tobramycin 80 mg/ 2mL (with preservative) excluding patients with sulfite allergy	Suitable for use in term neonates and children up to 18 years of age (exclude patients with sulfite allergy or acetylcysteine allergy)	
Inhaled use	Suitable (preservative free)	Contra-indicated (high risk of inducing bronchospasm with sodium metabisulfite and acetylcysteine excipients) . Discuss alternative inhaled treatment option with Infectious diseases specialist. Preservative free Tobramycin 80 mg/ 2mL or Tobramycin nebulas 300 mg/ 5mL is suitable alternatives – individual patient approval required for non LAM use.	
Intraperitoneal use	Suitable (preservative free)	Suitable for use in term neonates and children up to 18 years of age (exclude patients with sulfite allergy or acetylcysteine allergy)	
Intravesicular use (bladder dwells)	Suitable (preservative free) (individual patient approval required for non LAM use)	Suitable for use in term neonates and children up to 18 years of age (exclude patients with sulfite allergy or acetylcysteine allergy)	
Intraventricular, intrathecal, epidural	Suitable (preservative free) (Pharmacy Aseptic compounded dose)	Contra-indicated	Contra-indicated

References: [Medication Safety Notice Gentamicin Pfizer supply disruption \(sahealth.sa.gov.au\)](#) and [Patient Safety Communiqué PSC 18/2024 Disruption to supply of Australian registered, preservative free gentamicin injection \(health.qld.gov.au\)](#)