NSW Health

Disruption to supply – Gentamicin (Pfizer®) 80 mg/2 mL (as sulfate) injection BP ampoule

SAFETY NOTICE 016/24

Issue date:	1 July 2024
Content reviewed by:	Medication Safety Expert Advisory Committee (MSEAC) Antimicrobial Stewardship Expert Advisory Committee (AMSEAC) Medication Shortage Assessment and Management team (MSAM) Infection Prevention and Control (IPAC) and Healthcare Associated Infections (HAI) Program
Distributed to:	Chief Executives; Directors of Clinical Governance; Director, Regulation and Compliance Unit
KEY MESSAGE:	NSW Health facilities are informed of the anticipated disruption to the supply of gentamicin (Pfizer®) 80 mg/2 mL (as sulfate) injection BP ampoule and safety considerations associated with available alternatives.
ACTION REQUIRED BY:	Chief Executives, Directors of Clinical Governance
REQUIRED ACTION:	1. Distribute this Safety Notice to all relevant clinicians and clinical departments where gentamicin 80 mg/2 mL injection ampoules are held, prescribed, and administered, and include this Safety Notice in relevant handovers and safety huddles. 2. Ensure a system is in place to document actions taken in response to this Safety Notice. 3. Report any incidents associated with this disruption to supply into the local incident management system e.g., ims+. 4. Confirm receipt and distribution of this Safety Notice **within 72 hours** to: CEC-MedicationSafety@health.nsw.gov.au.
DEADLINE:	COB 3 July 2024
We recommend you also inform:	Directors, Managers and Staff of: • Infectious Disease and Microbiology Departments • Respiratory, Surgical, Anaesthetics, Paediatric and Emergency Departments • Pharmacy Services • Nursing/Midwifery Services • Medical Services • Drug and Therapeutics Committees All other relevant clinicians, departments and committees.
Website:	https://www.health.nsw.gov.au/sabs/Pages/default.aspx http://internal.health.nsw.gov.au/quality/sabs/index.html
Review date:	September 2025

Contact: Clinical Excellence Commission
02 9269 5500
CEC-MedicationSafety@health.nsw.gov.au

Disruption to supply – Gentamicin (Pfizer®) 80 mg/2 mL (as sulfate) injection BP ampoule

SN: 016/24

Situation

There is an anticipated disruption to the supply of gentamicin (Pfizer®) 80 mg/2 mL (as sulfate) injection BP ampoules (ARTG 11376) from 1 November 2024 to 31 March 2025 due to manufacturing issues. Refer to the Therapeutic Goods Administration (TGA) Medicine shortage reports database for the most up-to-date information about supply impact dates.

The alternative Australian registered product gentamicin (Noridem®) 80 mg/2 mL (as sulfate) solution for injection ampoule (ARTG 391250) is presented in a glass ampoule, and contains an additional excipient, **sodium metabisulfite**.

Background

Gentamicin is an aminoglycoside antibiotic widely used for:

- Short-term empiric therapy of serious Gram-negative infections; normally limited to less than 48 hours, and then changed to an alternative antibiotic based on culture results.
- Surgical prophylaxis.
- Directed therapy against confirmed sensitive pathogens, resistant to antibiotics more appropriate for longer term use.

Gentamicin is listed on the NSW Medicines Formulary with a restriction for use in accordance with the local antimicrobial stewardship policy.

Assessment

Gentamicin (Pfizer) is presented as a 'steriluer' (plastic ampoule) and is available in packs of 10 and 50. Remaining supply of the Pfizer brand is due to expire within this calendar year. Gentamicin (Noridem) is presented as a glass ampoule and is available in packs of 50 (see Figure 1). The Pfizer and Noridem products are approved for use for **intravenous** or **intramuscular** administration as per the Australian registered product information.

Important safety issues for consideration

1. The differences in presentation between the two products must be considered when administering the medication via the intravenous route, particularly when administering higher doses, as the risk for contamination with glass particulate is increased due to the number of ampoules required to prepare a dose. The Institute for Safe Medication Practices (ISMP) recommends the use of a filter needle when withdrawing intravenous medications from a glass ampoule (See ISMP Safe Practice Guidelines for Adult IV Push Medications). Therefore, a filter needle should be used when preparing the Noridem product for administration, or an in-line filter should be used if administering via intravenous infusion.

Contact: Clinical Excellence Commission
02 9269 5500
CEC-MedicationSafety@health.nsw.gov.au

2. The Noridem product contains an additional excipient, **sodium metabisulfite**. Sodium metabisulfite is a preservative commonly used in pharmaceuticals. The presence of this preservative should be considered as:
    a. Sodium metabisulfite can potentially trigger allergic reactions in individuals with sulfite sensitivity. This can cause adverse reactions such as asthma symptoms including wheezing, chest tightness and coughing and allergy like reactions including hay fever and hives. In rare cases, anaphylaxis may occur. For more information on sulfite sensitivity, refer to the Australasian Society of Clinical Immunology and Allergy – Sulfite Sensitivity Frequently Asked Questions (FAQ). Allergy status must be taken into consideration prior to administration. The Noridem product should be used with caution in neonates and paediatric patients where allergy status has not been established. Tobramycin can be substituted for gentamicin at the same doses for most indications – seek expert advice from Infectious Diseases/Microbiology. Supply of tobramycin 80 mg/2 mL ampoules remain available.
    b. Aminoglycosides can be administered via inhalation for the treatment of chronic pulmonary infections. However, the Noridem product **should not** be used via this route due to the risk of airway irritation associated with the presence of sodium metabisulfite. Tobramycin, an alternate aminoglycoside, is available and certain brands are approved for administration via inhalation. Supply of tobramycin (Sun) 300 mg/5 mL solution for inhalation ampoule remains available.
    c. It precludes administration via other off-label routes of administration which gentamicin may be used such as epidural and intrathecal.

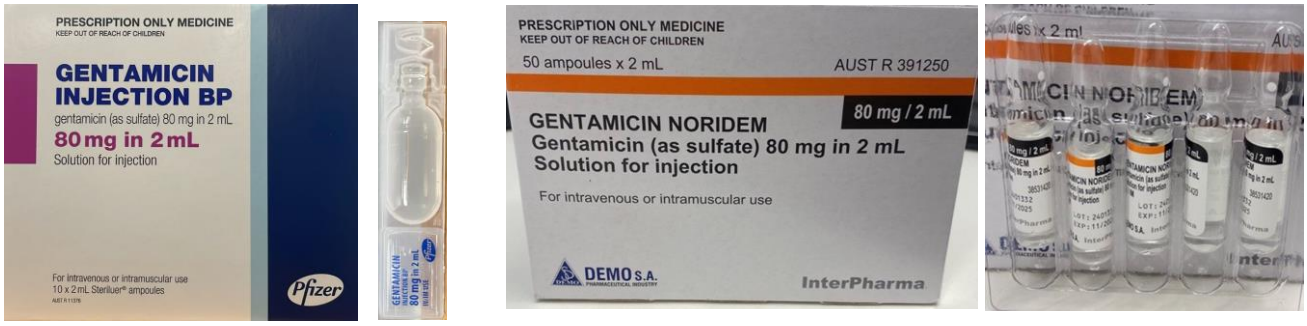

Figure 1: Images of gentamicin Pfizer (left) and Noridem (right) outer packaging and individual units.

Recommendations

- Review stock holdings of the Pfizer gentamicin product and develop a plan to changeover to the Noridem brand. **It is recommended not to use both presentations concurrently to avoid confusion.**
- Ensure clinicians are made aware of the differences in presentation between the Pfizer and Noridem products, additional excipients, and allergy risk (in individuals with sulfite sensitivity). Consider use of alerts or reference information within the electronic Medication

Management (eMM) system where appropriate. Note that some eMM systems may list the allergy as 'sul**ph**ite'.

- For those patients where use of the Noridem product is unsuitable or contraindicated, expert advice should be sought from Infectious Diseases/Microbiology regarding possible alternatives.
- A filter needle should be used when withdrawing intravenous gentamicin from a glass ampoule or an in-line filter should be used if administering via intravenous infusion. Ensure filter needles are readily available in treatment areas where gentamicin is administered.
- Utilise tobramycin products approved for administration via inhalation (for example, tobramycin (Sun) 300 mg/5 mL) in patients where nebulised doses of aminoglycosides are indicated.
- Regularly review prescriptions for gentamicin and assess ongoing need for use, in accordance with local antimicrobial stewardship policy.

Table 1: Comparison of Australian registered gentamicin and international alternatives

	Gentamicin (Pfizer) (ARTG 11376)	**Gentamicin (Noridem) (ARTG 391250)**
Country of registration	Australia	Australia
Active ingredient	Gentamicin (as sulfate) 80 mg/2 mL	Gentamicin (as sulfate) 80 mg/2 mL
Presentation	Steriluer® (plastic ampoule)	Glass ampoule
Pack size	10 x steriluer 50 x steriluer	50 x ampoule
Excipients	Disodium edetate Water for injections Sodium hydroxide Sulfuric acid	Disodium edetate **Sodium metabisulfite** Water for injections Sodium hydroxide Sulfuric acid
Storage requirements *When diluted*	Below 25°C Use immediately	Below 25°C Use immediately – as per NSW Health Infection Prevention and Control in Healthcare Settings Policy Directive (PD2023_025)
Labelling	English	English