Medication Shortage Communication

Information for health professionals in NSW public health organisations

Gentamicin 10 mg/1 mL injection – Disruption to Supply

Date of notice	27 April 2020
Status	Current
Details of the product(s) affected	DBL gentamicin sulfate 10 mg/1 mL injection ampoule ARTG 16339
Reason for the shortage	Manufacturing issue
Date shortage notified or apparent	20 Dec 2019
Estimated resupply dates	31 Jul 2020
Main therapeutic applications	• The 10 mg/1 mL strength of gentamicin is generally reserved for use in neonates and paediatric patients • Gentamicin is an aminoglycoside antibiotic widely used for empiric treatment of serious Gram-negative infections. Gentamicin therapy is normally limited to <48 hours, and then changed to an alternative antibiotic based on culture results. • Surgical prophylaxis • *P. aeruginosa* infections
Alternative agents	Teligent OU, the Canadian registered product of gentamicin sulfate injection 10 mg/1 mL (20 mg/2 mL) in 2 mL ampoules accessible via Link Medical Products P/L has been approved for limited supply under an exemption granted by the Therapeutic Good Administration under section 19A of the Therapeutic Goods Act 1989 until 31 August 2020. It is approved for intramuscular (IM) and intravenous (IV) routes of administration only. It contains the antioxidant/preservative sodium metabisulfite (see precautions below). Stock of gentamicin 10 mg/1 mL should be reserved for neonates where possible. Gentamicin is the preferred aminoglycoside for neonates as there is less experience with the use of tobramycin in this patient group. Tobramycin can be substituted for gentamicin at the same doses for all indications if necessary. Amikacin can also be considered as an alternative (however dosing differs to gentamicin and tobramycin). Refer to local epidemiology patterns and/or local infectious diseases advice to determine whether tobramycin or amikacin is the most suitable alternative in your facility.
Precautions associated with alternative products	• Teligent OU contains the antioxidant/preservative sodium metabisulfite (not present in the Australian

	product) and should not be used via inhalation due to risk of airway constriction (bronchoconstriction) • Whilst DBL gentamicin 10 mg/1 mL is not approved for use via the intraventricular route, there are reports of 'off-label' use. The presence of the antioxidant/ preservative sodium metabisulfite means that Teligent OU should not be administered via the intraventricular route. • The total dose and volume of Teligent OU is 20 mg/2 mL per ampoule in comparison to the 10 mg/1 mL volume of the DBL Gentamicin product. The strength is marked on the product labelling of Teligent OU as 10 mg/1 mL (20 mg/2 mL).
Anticipated effect of shortage on clinical practice	Action to address the shortage of gentamicin should be planned and implemented at a local level by the Antimicrobial Stewardship Committee and/or Drug and Therapeutics Committee.
Associated regulatory/policy issues	PD2013_043 Medication Handling in NSW Public Health Facilities
Key contacts	Clinical Excellence Commission (Medication Safety): CEC-MedicationSafety@health.nsw.gov.au HealthShare NSW (Product Critical Supply Manager): Rebecca.Robertson@health.nsw.gov.au