Medication Shortage Communication

Information for health professionals in NSW public health organisations

Dobutamine hydrochloride 250 mg/20 mL injection – disruption to supply

Date of notice	15 May 2020
Status	Current
Details of the product(s) affected	DBL DOBUTAMINE HYDROCHLORIDE 250 mg/20 mL injection vial ARTG 46451
Reason for the shortage	Unexpected increase in demand
Date shortage notified or apparent	8 May 2020
Estimated resupply dates	3 July 2020
Main therapeutic applications	Dobutamine is a synthetic catecholamine used in adults for the short-term treatment of cardiac failure secondary to acute myocardial infarction, or cardiac surgery.
Alternative agents	DOBUTREX **250 mg/50 mL** (5 mg/mL) solution for infusion vials are registered and approved for use in Switzerland and accessible via Link Medical Products. Dobutrex is approved for use in Australia by an exemption granted by the Therapeutic Good Administration (TGA) under section 19A of the Therapeutic Goods Act 1989 until 31 July 2020. The two alternative Australian registered dobutamine products that hospitals may have used previously; Dobutamine Sandoz (dobutamine 250 mg/20 mL) injection and Dobutrex (dobutamine 250 mg) powder for injection vial will be deleted from the market in 2020.
Precautions associated with alternative products	• The concentration of Dobutrex is 5 mg/mL, which is different to the Australian registered product (12.5 mg/mL). This means that Dobutrex **does not need dilution prior to use.** The undiluted vial contents (i.e. 50mL) should be administered as per local hospital protocol via intravenous infusion. • The packaging of Dobutrex is in German and French language. The active ingredient dobutamine appears on the label in German as 'Dobutaminum.' The strength is clearly displayed in English. Refer to the TGA S19A webpage listing for an image of the product packaging.
Anticipated effect of shortage on clinical practice	Action to address the shortage of dobutamine hydrochloride should be planned and implemented at a local level by the Drug and Therapeutics Committee. Health care professionals should be made aware of the differences in products and the associated precautions.
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): Caroline.Pfeffercorn@health.nsw.gov.au