13 November 2023

Shortage of DBL DOBUTAMINE HYDROCHLORIDE 250mg/20ml solution for injection and alternative supply arrangement under Section 19A of the *Therapeutic Goods Act, 1989*

Dear Healthcare Professional,

This communication is sent by ORSPEC Pharma to notify your organisation that due to the shortage of **DBL DOBUTAMINE HYDROCHLORIDE 250mg/20ml solution for injection (AUST R 46451).** ORSPEC Pharma has arranged the supply of an alternative product on a temporary basis.

Dobutamine 12.5 mg/ml (250mg/20mL) concentrate for solution for infusion (Hameln), is NOT registered in Australia and supply is granted under an exemption granted by the Therapeutic Goods Administration (TGA) under Section 19A of the *Therapeutic Goods Act, 1989* until **30 April 2024.**

Dobutamine 12.5 mg/ml (250mg/20mL) concentrate for solution for infusion (Hameln) is approved for use under Section 19A for the following indications:

> *Dobutamine Hydrochloride Injection is indicated in adults who require short-term treatment of cardiac failure secondary to acute myocardial infarction, or cardiac surgery.*

The s19A approved UK product is identical in active ingredient and strength to the Australian registered product. The differences between the products are noted below:

	ARTG product DBL DOBUTAMINE HYDROCHLORIDE 250mg/20ml solution for injection (AUST R 46451)	**S19A product** Dobutamine 12.5 mg/ml (250mg/20mL) concentrate for solution for infusion (Hameln)
Excipients	Sodium metabisulfite Water for injections	Sodium Metabisulfite Sodium Hydroxide Hydrochloric Acid Water for Injections Carbon Dioxide
Pack size	single vial	pack of 10 ampoules

Dobutamine 12.5 mg/ml (250mg/20mL) concentrate for solution for infusion (Hameln) is registered in the United Kingdom and is packaged in the English language. For dosing and administration information, please refer to the Australian Product Information for **DBL DOBUTAMINE HYDROCHLORIDE 250mg/20ml** available at https://www.ebs.tga.gov.au/

Adverse Event Reporting

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **Dobutamine 12.5 mg/ml (250mg/20mL) concentrate for solution for infusion (Hameln),** should be reported by healthcare professionals and patients to ORSPEC Pharma on 024 339 4239 or email at customerservice@orspecpharma.com. Alternatively, this information can be reported to the TGA at https://www.tga.gov.au/reporting-problems

Please forward this information to relevant staff members in your organisation.

For further information, please contact ORSPEC Pharma on 024 339 4239 or email customerservice@orspecpharma.com.

Yours sincerely,

Deon Scheepers
Managing Director
ORSPEC Pharma