22 February 2024

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 250mg/20mL solution for Injection (Slate Run), 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 **31 May 2024.**

Dobutamine 250mg/20mL solution for Injection (Slate Run) 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 USA product is identical in active ingredient and strength to the Australian registered product. The differences between the products are highlighted below:

	ARTG product DBL DOBUTAMINE HYDROCHLORIDE 250mg/20ml solution for injection (AUST R 46451)	**S19A product** Dobutamine 250mg/20mL solution for Injection (Slate Run)
Excipients	Sodium metabisulfite Water for injections	Sodium Metabisulfite Water for Injections Sodium Hydroxide or Hydrochloric Acid may be present for pH adjustment.
Reconstitution details	Dobutamine hydrochloride should not be used in conjunction with other agents or diluents containing sodium bisulfite.	Dobutamine injection should not be used in conjunction with other agents or diluents containing both sodium bisulfite and ethanol.
Presentation	1 vial per carton	10 vials per carton

For dosing and administration information, please refer to the Australian Product Information for **DBL DOBUTAMINE HYDROCHLORIDE 250mg/20ml solution for injection** 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 250mg/20mL solution for Injection (Slate Run),** 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 02 4339 4239 or email customerservice@orspecpharma.com.

Yours sincerely,

Deon Scheepers
Managing Director
ORSPEC Pharma