



3 August 2022

**Shortage of DBL ACETYLCYSTEINE, injection concentrate acetylcysteine 2 g/ 10 mL ampoule product and alternative supply arrangement under Section 19A of the Therapeutic Goods Act**

Dear Healthcare Professional,

This communication is sent by ORSPEC Pharma to notify your organisation that due to the shortage of **DBL ACETYLCYSTEINE injection concentrate acetylcysteine 2 g/ 10 mL injection ampoule (AUST R 121503)**. ORSEPC Pharma has arranged the supply of an alternative product on a temporary basis.

**ACETYLCYSTEINE SOLUTION USP 2000mg/10mL (200mg/mL)**, are 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 October 2022.

**ACETYLCYSTEINE SOLUTION USP 2000mg/10mL (200mg/mL)**, are approved for use under Section 19A for the following indications:

- *For the treatment of paracetamol overdose to protect against hepatotoxicity.*

**ACETYLCYSTEINE SOLUTION USP 2000mg/10mL (200mg/mL)**, are registered in the Canada and are packaged in English and French language. For dosing and administration information, Please refer to the Australian Product Information for acetylcysteine 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 **ACETYLCYSTEINE SOLUTION USP 2000mg/10mL (200mg/mL)**, should be reported by healthcare professionals and patients to ORSPEC Pharma on 024 339 4239 or email at [sas@orspecpharma.com](mailto:sas@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 [sas@orspecpharma.com](mailto:sas@orspecpharma.com).

Yours sincerely,

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A handwritten signature in black ink, appearing to read "Deon Scheepers".

Deon Scheepers  
Managing Director  
ORSPEC Pharma