

20th September 2023

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Dear Healthcare Professional

Shortage of QUILONUM SR lithium carbonate 450mg tablet, blister pack AUST R: 53377 and alternative supply arrangement under section 19A of the *Therapeutic Goods Act 1989*

The Australian registered medicine, **QUILONUM SR lithium carbonate 450mg tablet, blister pack AUST R: 53377** sponsored by **Aspen Pharmacare Australia Pty Ltd** is currently unavailable or in short supply.

LINK has been able to arrange supply of an alternative product **Lithium carbonate extended-release tablets, USP 450mg (Rising)** on a temporary basis. This product is NOT registered in Australia and supply is authorised under an approval granted by the Therapeutic Goods Administration (TGA) under section 19A of the *Therapeutic Goods Act 1989* until **31st January 2024** for the following indication(s):

- Lithium is indicated in the treatment of acute episodes of mania and hypomania and for the prophylaxis of recurrent manic-depressive illness.*

Lithium carbonate extended-release tablets, USP 450mg (Rising) is registered and marketed in the United States of America and therefore all labelling is in English.

Please note the following information regarding differences between **Lithium carbonate extended-release tablets, USP 450mg (Rising)** and **QUILONUM SR lithium carbonate 450mg tablet, blister pack AUST R: 53377**

	ARTG registered medicine: QUILONUM SR lithium carbonate 450mg tablet, blister pack AUST R: 53377	Section 19A approved medicine: Lithium carbonate extended-release tablets, USP 450mg (Rising)
Excipients	povidone maize starch lactose monohydrate gelatin carmellose calcium purified talc calcium behenate magnesium stearate, titanium dioxide macrogol 6000 Edudragit E 100 PI (1753)	sodium alginate sodium starch glycolate povidone ferric oxide yellow magnesium stearate
Container	Blister pack	Bottle of loose tablets

Please refer to the Australian Product Information for **QUILONUM SR lithium carbonate 450mg tablet, blister pack AUST R: 53377** available at <https://www.ebs.tga.gov.au> when prescribing and administering **Lithium carbonate extended-release tablets, USP 450mg (Rising)**

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 **Lithium carbonate extended-release tablets, USP 450mg (Rising)** should be reported by healthcare professionals and patients to the LINK healthcare Pharmacovigilance at pv@linkhealthcare.co or 1800 181 060. Alternatively, this information can be reported to the TGA at <https://www.tga.gov.au/reporting-problems>

Any product complaints regarding **Lithium carbonate extended-release tablets, USP 450mg (Rising)** should be reported to LINK on 1800 161 181.

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

For further information, please contact LINK on 1800 161 060 or email customerservice@linkhealthcare.com.au.

Yours faithfully



Kay Roweth
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Link Healthcare