

This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

This English version is intended to be a reference material to provide convenience for users.

In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of PRECAUTIONS

Lithium carbonate

November 13, 2024

Therapeutic category

Psychotropic agents

Non-proprietary name

Lithium carbonate

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revision
11.ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11.ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Drug-induced hypersensitivity syndrome</u> <u>Initial symptoms of rash and pyrexia, followed by serious delayed</u> <u>symptoms of hypersensitivity accompanied by hepatic impairment,</u> <u>swollen lymph nodes, increased white blood cell, eosinophilia, and</u> <u>appearance of atypical lymphocytes may occur. Symptoms are often</u> <u>accompanied by virus reactivation, such as human herpes virus type</u> <u>6 (HHV-6). Caution is required for recurrence or prolongation of rash,</u> <u>pyrexia, hepatic impairment, etc. that may occur even after</u> <u>discontinuation of administration.</u>

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.