Summary of Investigation Results

Lithium carbonate

November 13, 2024

Non-proprietary name

Lithium carbonate

Brand name (marketing authorization holder)

Limas tablets 100, 200 (Taisho Pharmaceutical Co., Ltd.), and the others

Japanese market launch

February 1980

Indications

Mania, manic state in manic depressive illness

Summary of revisions

“Drug-induced hypersensitivity syndrome” should be added to the 11.1 Clinically Significant Adverse Reactions in 11. ADVERSE REACTIONS.

Investigation results and background of the revision

Cases involving drug-induced hypersensitivity syndrome were evaluated. Cases for which a causal relationship between lithium carbonate and drug-induced hypersensitivity syndrome was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

Reference: Number of cases* and patient mortalities involving drug-induced

hypersensitivity syndrome reported in Japan and overseas

A total of 19 cases have been reported in Japan to date (including 4 cases for which a causal relationship between the drug and the event was reasonably possible).

One instance of patient mortality has been reported in Japan to date. (A causal relationship between the drug and death subsequent to the event could not be established for this case.)

A total of 6 cases have been reported overseas to date (including 1 case for which a causal relationship between the drug and the event was reasonably possible).

No patient mortalities have been reported overseas to date.

*Cases collected in the PMDA's database for adverse drug reactions, etc. reports

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).