Attachment 1
June 16, 2026

【Therapeutic category】Psychotropic agents
【Non-proprietary name】Lithium carbonate
【Safety measure】PRECAUTIONS should be revised.

A revised description is underlined.

Current	Revision
2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.) Pregnant women or women who may be pregnant	2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.) (Deleted)
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS (N/A)	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.4 Patients with Reproductive Potential When this drug is used in women with childbearing potential, the teratogenicity of this drug should be adequately explained, and the appropriateness of using this drug should be carefully determined. The dose–response relationship between this drug and the risk of congenital anomaly is unclear.
9.5 Pregnant Women This drug should not be administered to pregnant women or women who may be pregnant. Teratogenic effects have been reported in animal studies (rats and mice), and an increase in the frequency of heart malformations	9.5 Pregnant Women This drug should not be administered to pregnant women or women who may be pregnant unless it is considered necessary for the treatment. Teratogenic effects have been reported in animal studies (rats and mice),

have been reported in humans. An abnormally elevated serum concentration of lithium may occur immediately before delivery in women in late pregnancy.	and the occurrence of heart malformations has been reported in humans. This drug should be used only in patients for whom administration of this drug is considered appropriate, under the supervision of a physician who has knowledge and experience in the treatment of bipolar disorder and can adequately manage and explain the following risks, etc. of this drug, in collaboration with medical institutions that can perform appropriate perinatal management of pregnant women, fetuses, and neonates. • The serum concentration of lithium following administration of lithium carbonate may change with pregnancy, which may affect the treatment response. When this drug is administered to pregnant women, serum lithium concentration should be frequently measured and the patients' condition, etc. should be carefully monitored. An abnormally elevated serum concentration of lithium may occur immediately before delivery in late pregnancy. • Neonatal drug withdrawal syndrome or lithium poisoning may occur in neonates born to pregnant women exposed to lithium.

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

[References] Patorno,E.,et al.:N.Engl.J.Med. 2017;376:2245-2254

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