

## Lithium Carbonate

*Lithium Carbonate*

250 mg Capsules

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### What is in this leaflet

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**Please read this leaflet carefully before you start taking Lithium Carbonate.**

This leaflet answers some common questions about Lithium Carbonate. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Lithium Carbonate against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine. You may need to read it again.**

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### What Lithium Carbonate Capsules are used for

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Lithium Carbonate Capsules are used to both treat and prevent:

- Mania - a mental illness characterised by abnormal excitability and instability.
- Bipolar depression - a mental illness where mood alternates between up (manic) and down (depression).
- Recurrent affective disorders characterized by recurrent depressive episodes where mood may be down in late autumn and winter, alternating with normal mood the rest of the year.

Your doctor may have prescribed Lithium Carbonate for another reason.

**Ask your doctor if you have any questions about why Lithium Carbonate has been prescribed for you.**

This medicine is available only with a doctor's prescription.

**There is no evidence this medicine is addictive.**

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### Before you take Lithium Carbonate

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#### ***When you must not take it***

**Do not take Lithium Carbonate if you have an allergy to:**

- Any medicine containing lithium.
- Any of the ingredients listed at the end of this leaflet.

**Some of the symptoms of an allergic reaction may include:**

- Asthma, shortness of breath, wheezing.
- Swelling of the face, lips, or tongue which may lead to difficulty swallowing or breathing.
- Rash, itching or hives.
- Fainting.

**Do not take Lithium Carbonate if:**

- You are ***taking other medicines***, including medicines that you buy without a prescription without telling your doctor or pharmacist.
- You have severe kidney disease.
- You have low levels of sodium in your body – e.g., if you are on a low salt diet.
- You have Addison's disease - a disease due to low activity of the adrenal glands.
- You have significant cardiovascular disease.
- If you have an under-active thyroid gland that is not being treated.

- You have the genetic disorder Brugada syndrome or a family history of Brugada syndrome. This is an abnormal condition of the heart that can make it stop beating.

**Do not take this medicine if you are pregnant.**

It may affect your developing baby if you take it during pregnancy.

**Do not breastfeed if you are taking this medicine.**

The active ingredient in Lithium Carbonate passes into breast milk and there is a possibility that your baby may be affected.

**Do not give this medicine to a child under the age of 12 years.** Safety and effectiveness in children younger than 12 years have not been established.

**Do not take it after the expiry date (EXP) printed on the back.** If you take it after the expiry date has passed, it may not work as well.

**Do not take it if the packaging is torn or shows signs of tampering or if the capsules show visible signs of deterioration.**

**If you are not sure whether you should start taking Lithium Carbonate talk to your doctor.**

***Before you start to take it***

The amount of lithium absorbed by your body is determined by individual characteristics and factors such as kidney function, diet, health status, other medication and the blood-testing regimen, which you will undergo periodically. It is important your doctor determines the right amount of lithium for you personally because the margin between the desired response for you and the toxic response is narrow.

**High concentrations of lithium in your body may be lethal.**

It is therefore important, that you **follow your doctor's instructions carefully** and you and your family are able to **recognise symptoms of lithium intoxication.**

Tell your doctor if:

1. You have allergies to:
  - Any other medicines, including any other substances, such as foods, preservatives or dyes.
2. You have, or have had, the following medical conditions:
  - Heart disease.
  - Kidney problems.
  - The genetic disorder Brugada syndrome, a family history of Brugada syndrome, or a family history of cardiac arrest or sudden death.
  - An under-active thyroid gland that is not being treated.
  - Addison's disease – a disease due to low activity of the adrenal glands.

Poor kidney function impairs lithium excretion and may worsen heart problems. Your doctor will discuss the risks and benefits of taking this medicine if you have these conditions.

3. You are pregnant:
  - Tell your doctor straight away.
  - Do not take Lithium Carbonate Capsules if you are pregnant, especially in the first 3 months of your pregnancy.

If your doctor decides that you should have Lithium Carbonate Capsules while you are pregnant, they will:

- Keep a close eye on the level of lithium in your blood. This is because your kidney works differently while you are pregnant.
  - Arrange for appropriate tests before your baby is born.
4. Intend to or could become pregnant:
    - Talk to your doctor before taking this medicine. It is very important that you speak with your doctor about your treatment well before you become pregnant.
    - You should use an effective method of contraception while taking Lithium Carbonate.
  5. You are breastfeeding or planning to breastfeed:

- Do not breast-feed if you are taking Lithium Carbonate. It is known that Lithium Carbonate can pass into the mother's milk.

6. You have any of the following:

- Stomach flu
- Urinary infection
- Cold or flu

7. You are planning, or have already had weight loss surgery, as a lower dose of lithium may be required. Your doctor will monitor the level of lithium in your blood and adjust your dose accordingly.

**If you have not told your doctor about any of the above, tell them before you start using Lithium Carbonate.**

**It is not recommended Lithium Carbonate Capsules be taken during pregnancy or while breastfeeding.**

The infant may develop heart abnormalities and lithium intoxication.

Your doctor will discuss the risks and benefits of taking this medicine while you are pregnant.

### ***Taking other medicines***

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Lithium Carbonate.

Lithium Carbonate may interfere with how well other medicines work and vice versa.

Some medicines may cause an increase in the blood levels of lithium resulting in lithium toxicity, or decrease blood levels, making it not as effective for your condition.

### **Medicines that may increase lithium concentration include:**

- Selective Serotonin Re-Uptake Inhibitors (SSRIs) - medicines used to treat depression.
- Antibiotics: Metronidazole, Tetracyclines
- Topiramate.
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) – Medicines used to alleviate pain, inflammation and fever (e.g. aspirin, ibuprofen, diclofenac).
- Angiotensin-Converting Enzyme (ACE) Inhibitors – medicines used to treat high blood pressure and heart failure.
- Thiazide Diuretics - medicines that remove sodium from your body via urination.
- Spironolactone.
- Frusemide.
- Angiotensin-II Receptor Antagonists - medicines used to treat high blood pressure.
- Steroids.

### **Medicines that may decrease lithium concentration include:**

- Xanthines such as theophylline and caffeine.
- Sodium bicarbonate (baking soda) and sodium chloride (table salt).
- Psyllium or Ispaghula husk such as Metamucil and Mucilax.
- Urea and mannitol.
- Acetazolamide.
- Empagliflozin.
- Dapagliflozin.

### **Medicines that may cause nerve damage include:**

- Neuroleptics - A type of sedative such as risperidone, clozapine, phenothiazines and haloperidol when used with Lithium Carbonate, may lead to, in rare cases, neurotoxicity giving symptoms such as confusion, disorientation, lethargy and tremor.
- SSRIs, sumatriptan and tricyclic antidepressants used with Lithium carbonate has been associated with neurotoxicity.

- Calcium Channel Blockers such as verapamil, diltiazem and enalapril – (medicines used to treat heart problems and high blood pressure) when used with Lithium Carbonate may lead to neurotoxicity giving symptoms such as ataxia, confusion and somnolence, which are reversible after discontinuation of the drug.
- Carbamazepine or phenytoin when used with Lithium carbonate may lead to dizziness, somnolence, confusion and cerebellar symptoms.
- Methyldopa.

#### **Other medicines** that may affect lithium

- Neuromuscular Blocking Agents - medicines used to induce muscle paralysis.
- Iodide.
- Baclofen.
- Cotrimoxazole.
- Aciclovir.
- Prostaglandin Synthetase Inhibitors - medicines used to treat inflammation and pain.
- Medicines that may increase serotonin levels such as fluoxetine and sertraline.
- Medicines that can bring about an epileptic fit such as antihistamines, stimulants or antidepressants.
- Medicines such as quinidine, disopyramide, amiodarone, cisapride.
- Medicines such as thioridazine or amisulpride.
- Antibiotics such as erythromycin.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Lithium Carbonate Capsules.

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## **How to take Lithium Carbonate**

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**Follow all directions given to you by your doctor or pharmacist carefully.** They may differ from the information contained in this leaflet.

### ***How much to take***

Your doctor will tell you how many Lithium Carbonate Capsules you should take each day. This depends on your condition, simultaneous use of other medicines and the results of the tests carried out by your doctor in order to determine the optimal response for you. It is not unusual for your doctor to alter the dose from time to time.

**If you do not understand the instructions on the label, ask your doctor or pharmacist for help.**

### ***How to take it***

**Swallow the prescribed dose of capsules with some water.** It is recommended to take Lithium Carbonate with food, as this causes less nausea than on an empty stomach. Lithium Carbonate Capsules may be taken before or after meals.

### ***When to take it***

You must take your dose at exactly the set times as prescribed by your doctor. This is necessary to keep the amount of lithium in your blood constant.

### ***How long to take it***

Lithium Carbonate Capsules are not a cure. To control mood swings you may need to take it for a long period of time.

### ***If you forget to take it***

**Do not double the dose to make up for the one you missed.** If it is less than 2 hours until your next dose, skip the dose you have missed but be sure to take the next dose when you are meant to.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering your dose, ask your pharmacist for some hints.

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# While you are taking Lithium Carbonate

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## ***Things you must do***

**Tell all doctors and pharmacists who are treating you that you are taking Lithium Carbonate Capsules.**

**Tell your doctor immediately if you become pregnant while taking Lithium Carbonate Capsules.**

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.** It may interfere with the results of some tests.

Tell your doctor if you feel Lithium Carbonate Capsules are not controlling your mood swings.

**Be sure to keep all your appointments with your doctor so that your progress can be checked and blood tests can be conducted. Your dose of lithium has to be monitored along with blood concentrations of sodium.** A reduction in sodium intake leads to retention of lithium while an increased sodium intake increases lithium excretion. You should avoid any form of diet, foods or medicines that may cause a marked change in sodium concentration. Sodium is found in common table salt and preserved foods. You should also be examined for abnormal thyroid (a gland situated in your neck) function.

Watch for symptoms of lithium intoxication. These are listed below under side effects.

## ***Things you must not do***

**Do not stop taking Lithium Carbonate Capsules or change the dose without first checking with your doctor.**

**Do not let yourself run out of medicine over the weekend or on holidays.**

**Do not give Lithium Carbonate Capsules to anyone else even if they have the same condition as you.**

**Do not use Lithium Carbonate Capsules to treat other complaints unless your doctor says to.**

**Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.**

## ***Things to be careful of***

Lithium Carbonate Capsules may impair your ability to drive or use machinery. Care should be taken until you know how this medicine affects you.

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## **In case of overdose**

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### ***If you take too much (overdose)***

**Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Lithium Carbonate.**

**Do this even if there are no signs of discomfort or poisoning.** You may need urgent medical attention.

The symptoms of overdose are reported to be mainly related to the digestive and nervous systems and include: abdominal pain, loss of appetite and nausea, sickness, diarrhoea, blurred vision, passing a lot of water, lightheadedness, tremor, muscle twitching, muscle weakness or drowsiness and feeling very tired. In extreme cases unconsciousness, coma, fits, heart rhythm problems (slow or irregular heartbeat) and kidney failure can occur.

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## **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Lithium Carbonate.**

**You and your family must be able to recognise the symptoms of lithium intoxication. Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Lithium Carbonate Capsules.**

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

**Do not be alarmed by this list of possible adverse effects.** You may not experience any of them.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor if you notice any of the following:**

- Lack of interest.
- Tiredness.
- Reduced concentration.
- Rigid posture.
- Aching body.
- Indigestion.
- Constipation.
- Weight gain.
- Swelling.
- Acne.
- Itchy skin and rash.
- Flushing.
- Stuffy nose.
- Headache.
- Enlarged thyroid gland.
- Nausea.
- Abdominal pain.
- Changes in skin condition
- Hair loss
- Itchiness

**These are mild to moderate side effects of lithium intoxication.**

**Memory impairment may occur during long term use.**

**Severe adverse effects may be fatal and require hospitalisation. Seek medical treatment immediately. Symptoms are:**

- Ill looking, pinched, drawn, grey and cold.

- Impaired consciousness.
- Enhanced reflexes.
- Convulsions and epileptic seizures.
- Shortness of breath.
- Severe abdominal pain
- Vomiting
- Diarrhoea
- Drowsiness or sluggishness
- Weak muscles
- Unsteady walking
- Lack of co-ordination
- Tremors
- Muscle twitchings
- Dry mouth
- Blurred vision
- Ringing in the ears
- Decreased appetite
- Metallic taste
- Change in heart rate, for example a faster, slower or irregular heartbeat.
- Kidney problems, for example, passing a lot of urine, feeling thirsty and swollen ankles.
- Speech difficulty
- Disorientation
- Delusions and hallucinations
- If you have a high fever, agitation, confusion, trembling, and abrupt contractions of muscles, as these may be signs of a rare condition called serotonin syndrome

**If you develop the following, you may have had a serious allergic reaction to Lithium Carbonate:**

- Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing.
- Hives
- Fainting

**The following are signs of a syndrome known as DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms alternatively hypersensitivity syndrome):**

- Widespread rash
- High body temperature
- Liver enzyme elevations
- Enlarged lymph nodes

Lithium poisoning has been associated with permanent kidney, heart, brain and nervous system damage.

These may be serious side effects of Lithium Carbonate and you may need urgent medical attention. Serious side effects are uncommon.

**Tell your doctor if you notice any other effects.** Other adverse effects not listed above may also occur in some patients.

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## After taking Lithium Carbonate

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### *Storage*

**Keep your Lithium Carbonate Capsules in the original container and protect from light and moisture until it is time to take them.**

If you take the medicine out of its container, it may not keep well.

**Keep Lithium Carbonate Capsules in a cool dry place where the temperature stays below 30°C.**

**Do not store it, or any other medicine, in a bathroom or near a sink.**

**Do not leave it in the car or on windowsills.**

Heat and dampness can destroy some medicines.

**Keep Lithium Carbonate Capsules where children cannot reach them.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### *Disposal*

If your doctor tells you to stop taking Lithium Carbonate Capsules, or the medicine has passed its expiry date, **ask your pharmacist what to do with any capsules left over.**

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## Product description

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### *What it looks like*

250 mg capsule: a size one capsule having a green cap and clear body filled with a white powder. It comes in plastic bottles containing 100 capsules.

### *Ingredients*

#### Active ingredient(s):

Each Lithium Carbonate capsule contains 250 mg of lithium carbonate.

#### Inactive ingredients:

Lithium Carbonate Capsules contain lactose monohydrate, maize starch, magnesium stearate, gelatin, EEC Quinoline Yellow E104, FD&C Blue #1 E133 and FD&C Yellow # E110

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## Sponsor details

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**Lithium Carbonate** is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd

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## Date of preparation

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03 October 2024

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