

LITHICARB FC

Lithium carbonate Tablets, film-coated 250 mg and 40 0mg



What is in this leaflet

This leaflet answers some common questions about LITHICARB FC. It does not contain all the information available on this medicine. 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 using LITHICARB FC against the benefits expected it will have for you. If you have any concerns about using this medicine, ask your doctor or pharmacist. Keep this leaflet. You may want to read it again.

What LITHICARB FC is used for and how it works

Your LITHICARB FC tablets contain the active ingredient lithium carbonate. Lithium carbonate provides a source of lithium ions, which compete with sodium ions at various sites in the body.

LITHICARB FC is used to treat patients with mental conditions (e.g. over-activity and mood changes) and recurring bipolar disorder. LITHICARB FC is also used in the prevention of mood problems.

Your doctor may, however, prescribe LITHICARB FC for another reason. Ask your doctor if you have any questions about why LITHICARB FC has been prescribed for you.

There is no evidence that LITHICARB FC is addictive.

LITHICARB FC is available on prescription from your doctor.

Before you take LITHICARB FC

When you must not take it

Do not take LITHICARB FC if:

- **You are allergic to lithium carbonate or any of the ingredients listed at the end of this leaflet**

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

- **You have a heart or kidney problem**
- **You have low activity of the adrenal gland (eg Addison's disease)**
- **You have an underactive thyroid gland**
- **If you have low levels of sodium in your body (eg if you are dehydrated or on a low salt diet)**
- **If you are pregnant or breastfeeding**
- **If you intend to become pregnant or to breastfeed. Lithium carbonate may be harmful to the foetus and newborn baby. It is therefore strongly recommended that lithium carbonate therapy is not started if pregnant or breastfeeding. Lithium carbonate is secreted into breast milk, therefore bottle-feeding is recommended.**

Before you take it

Tell your doctor:

- If you are taking any other lithium supplements or any other

medicines that you think may contain lithium

- If you have a heart or kidney problem
- If you have any thyroid or parathyroid problems
- If you do not have a balanced diet
- If you plan to have surgery
- If you weigh less than 50 kg

Your doctor will arrange for blood tests and other health checks to be carried out prior to and during your treatment with LITHICARB FC.

Treatment with LITHICARB FC requires regular monitoring of blood lithium levels. Your doctor will arrange for the necessary blood tests to be carried out. Frequent blood tests are required at the start of treatment. The period between blood tests is then increased gradually up to about 3 months. Additional blood tests may be required following alteration of your dosage, change in your condition, or following a significant change in your sodium (e.g. salt) or fluid intake.

Taking other medicines

If you are taking any other medicines, including any you get without a prescription from a pharmacy, supermarket or health food shop, it is very important you tell your doctor or pharmacist.

Medicines that may increase lithium concentration include:

- Selective serotonin re-uptake inhibitors (SSRIs) - medicines used to treat depression
- Metronidazole – a medicine used to treat infections (antibiotic)
- Tetracyclines – a medicine used to treat infections (antibiotic)
- Topiramate – a medicine used to treat certain types of seizures
- Non-steroidal anti-inflammatory drugs (NSAIDs) - medicines

- used to alleviate pain, inflammation and fever
- Medicines used to treat high blood pressure and heart failure. This could be any one of the following medicines:- amiloride, bendrofluazide, bumetanide, chlorthiazide, chlorthalidone, eplerenone, frusemide, spironolactone, quinapril, candesartan, losartan, indapamide, captopril, cilazapril, enalapril or a combination of these.
 - Other drugs affecting electrolyte balance may alter lithium excretion, e.g. steroids.

Substances that may decrease lithium concentrations:

- Xanthines, such as theophylline (in some asthma preparations) and caffeine (in some cold and flu and pain preparations as well as in coffee, tea and some fizzy drinks)
- Sodium bicarbonate (baking soda) and sodium chloride (table salt)
- Psyllium or Ispaghula husk such as Metamucil and Mucilax
- Urea
- Mannitol
- Acetazolamide

Medicines that may cause nerve damage include:

- Neuroleptics - such as risperidone, clozapine, phenothiazines and haloperidol - medicines used to treat certain mental disorders
- SSRIs, sumatriptan and tricyclic antidepressants
- Calcium channel blockers, such as verapamil and diltiazem - medicines used to treat heart problems and high blood pressure
- Carbamazepine or phenytoin
- Methyl dopa

Other medicines:

- Neuromuscular blocking agents - medicines used to induce muscle paralysis
- Thioridazine - a medicine used to treat certain mental and emotional disorders

- Iodide – a form of iodine
- Baclofen – a muscle relaxant and antispastic agent
- Cotrimoxazole - a medicine used to treat infections (antibiotic)
- Aciclovir – a type of medicine used to treat viral infections
- Prostaglandin synthetase inhibitors - medicines used to treat inflammation and pain

These medicines may be affected by LITHICARB FC or may affect how well LITHICARB FC works. You may need different amounts of your medicines or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking LITHICARB FC.

How to take LITHICARB FC properly

How much to take

Your doctor will tell you exactly how much LITHICARB FC you should take each day. This will depend on your condition and whether you are taking any other medication at the same time. The doctor will also carry out tests to determine the dose that is best for you. It is not unusual for your doctor to alter the dose from time to time. It is important that you take LITHICARB FC as directed by your doctor, as the directions given by the doctor may differ from the information contained in this leaflet.

Do not take more than the recommended dose.

LITHICARB FC is usually given as a single daily dose, in the morning or evening. Alternatively, the dose may be divided and given morning and evening.

LITHICARB FC should be swallowed whole with a glass of water. They are not to be crushed, chewed or swallowed with hot water. It is advisable to take Lithicarb FC with food as it causes less nausea than on an empty stomach.

During treatment with LITHICARB FC you should try to stick to a balanced diet and fluid intake. This will help you maintain a stable salt and water balance. This is particularly important in hot weather and during periods of illness.

The use of LITHICARB FC is not recommended for children.

How long to take it

LITHICARB FC helps to control your condition but does not cure it. Therefore, LITHICARB FC must be taken everyday. Continue taking LITHICARB FC for as long as your doctor prescribes.

If you forget a dose

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking LITHICARB FC as you would normally.

It is important that you do not take more than one dose at a time to make up for the doses that you missed. This may increase the chance of you getting an unwanted side effect.

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

Taking your medicine at the same time each day may help you to remember to take it regularly. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking LITHICARB FC

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking LITHICARB FC.

Tell your doctor or pharmacist that you are taking LITHICARB FC before you start any new medicine.

Tell your doctor if you develop a skin rash or hives, become unwell

or you become pregnant while taking LITHICARB FC.

Tell your doctor if you have an infection such as a cold, influenza, gastrointestinal problem or a urinary infection which may affect your fluid balance.

If you are going to have a surgery, tell the surgeon or anaesthetist that you are taking LITHICARB FC.

If you are going to have any blood tests, tell your doctor that you are taking LITHICARB FC.

Things you must not do

Do not take LITHICARB FC to treat any other complaints unless your doctor tells you to.

Do not stop taking LITHICARB FC or lower the dose without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

LITHICARB FC may cause dizziness or tiredness in some people. Be careful when driving, operating machinery or performing jobs that need you to be alert, until you are certain that LITHICARB FC does not affect your performance.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking LITHICARB FC. All medicines can have some unwanted effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you experience some of the side effects.

The side effects of LITHICARB FC are usually related to high levels of lithium ions in the blood. Elderly patients may be more sensitive to these side effects.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Mild gastrointestinal disturbances, nausea, dizziness, muscle weakness and a dazed feeling may occur on commencing treatment with LITHICARB FC, but frequently disappear once the dose is stabilised
- Tremor of the hands
- Weight gain and/or swelling
- Increased urine output and mild thirst
- Skin conditions including acne, psoriasis (thickened patches of red skin that may be scaly), rashes and leg ulcers
- Hair loss
- Dry mouth
- Long term treatment may be associated with disturbances of calcium levels, thyroid function, parathyroid function and memory impairment.
- Impairment of kidney function
- Episodes of nausea and vomiting, or other conditions that may lead to salt or water depletion (including severe dieting)
- Impotence/sexual dysfunction
- Loss of appetite
- Slow heart rate
- Changes in heart rhythm

Tell your doctor immediately if you experience:

- Excessive urine output or thirst
- Muscle weakness
- Lack of co-ordination
- Drowsiness or lethargy
- Giddiness
- Shortness of breath
- Ringing in the ears
- Blurred vision
- Slurred speech
- Disorientation
- Tremor or muscle twitching
- Convulsions and epileptic seizures
- Swelling of the tongue, mouth, throat, face or lips
- Excessive mouth watering
- Diarrhoea and vomiting.

If these symptoms occur stop taking your tablets immediately and report to your doctor for a blood test.

These side effects are rare but serious. You may need urgent medical attention.

The list of side effects mentioned above is not complete. If you should suffer from any of these side effects or any other undesired effect please tell your doctor or pharmacist.

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

In case of overdose

You should only take the number of tablets that you have been told.

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any LITHICARB FC by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the container of LITHICARB FC with you if you can.

Keep telephone numbers for these places handy.

Storage conditions

Do not take this medicine after the expiry date shown on the label or if the packaging shows signs of tampering.

Keep your LITHICARB FC tablets in the container until it is time to take them.

Store below 25°C and out of reach of children. Avoid exposure to heat, light and moisture.

Do not store LITHICARB FC, or any other medicine, in the bathroom or near a sink.

Disposal

If your doctor tells you to stop taking LITHICARB FC or if the tablets have passed the expiry date, ask your pharmacist what to do with the remaining medicine.

Product Description

What LITHICARB FC tablets look like:

LITHICARB FC 250 mg tablets are white, round tablets that are marked with "LC" breakline "250" on one side.

LITHICARB FC 400 mg tablets are white, round tablets that are marked with "LC" breakline "400" on one side.

Each LITHICARB FC tablet contains the active ingredient, lithium carbonate.

Both LITHICARB FC 250 mg and LITHICARB FC 400 mg tablets also contain lactose, maize starch, povidone, sodium starch glycollate, magnesium stearate, hypromellose, diethyl phthalate and carnauba wax.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

Date of information

09 June 2014
(Based on datasheet dated 09 June 2014)