

PACKAGE LEAFLET: INFORMATION FOR THE USER

**LITHIUM CARBONATE
EXTENDED RELEASE TABLETS
300MG / 400MG / 450MG
TAJ PHARMA**

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

WHAT IS IN THIS LEAFLET:

1. What LITHIUM CARBONATE is and what it is used for
2. What you need to know before you take LITHIUM CARBONATE
3. How to take LITHIUM CARBONATE
4. Possible side effects
5. How to store LITHIUM CARBONATE
6. Contents of the pack and other

information.

1. WHAT LITHIUM CARBONATE IS AND WHAT IT IS USED FOR

LITHIUM CARBONATE 400 mg controlled release tablets contain lithium carbonate, which is used to treat and prevent mania or manic depressive illness and recurrent depression in adults. It is sometimes used to treat other behavioural disorders.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LITHIUM CARBONATE DO NOT TAKE LITHIUM CARBONATE:

- if you are allergic to lithium or any of the other ingredients of this medicine (listed in section 6)
- if you have serious kidney disease
- if you have hypothyroidism (low thyroid hormones) that is difficult to treat
- if you have problems with the rhythm of your heart
- if you have a condition called Brugada syndrome (a hereditary syndrome that affects the heart), or if anyone in your family has had Brugada syndrome
- if you have low sodium levels in your body. This can happen if you are dehydrated, on a low sodium diet, or if you have an illness called 'Addison's disease' this happens when your body does not produce enough hormones and therefore making you feel tired,

- weak, lightheaded and areas of your skin may go darker
- if you are breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking LITHIUM CARBONATE:

- if you have epilepsy and take medicines to treat it
- if you take antipsychotic medications
- if you have heart disease
- if you develop persistent headaches and or visual disturbances
- if you have low amounts of potassium, magnesium and calcium in your blood - your doctor will tell you this.

Kidney tumours:

Patients with severe kidney impairment who received lithium for more than 10 years may have a risk of developing a benign or malignant kidney tumour (microcysts, oncocytoma or collecting duct renal carcinoma).

Whilst you are taking LITHIUM CARBONATE

Before you start taking LITHIUM CARBONATE, and while you are taking it, your doctor should check on you're:

- kidneys and urine
- thyroid
- Heart.

It is important that you tell your doctor if you notice any side effects or are ill whilst you are taking LITHIUM CARBONATE. These could be early signs that your doctor should give you

another check-up. Elderly patients should take particular care about this. Possible side effects are described later in this leaflet.

Other situations where you may need your blood monitoring more often are:

- if there is a change in your dose or you change brands of lithium tablets
- you have an infection or other existing disease/disorder
- large changes in the amount of fluid you drink or sodium (salt) you consume
- taking other medicines
- you have kidney disease that you have been told by your doctor is not serious.

Other medicines and LITHIUM CARBONATE

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should tell your doctor if you are taking any of the following:

These medicines may **increase** the amount of lithium in your body making you more likely to have side effects:

Any medicine which may cause kidney problems

- antibiotics called tetracyclines, metronidazole, co-trimoxazole, trimethoprim and spectinomycin
- non-steroidal anti-inflammatory drugs (e.g. diclofenac or ibuprofen) including COX- II inhibitors such as celecoxib. These are used for rheumatism and for other pains. You can also get pain killers of this type without a prescription so check with your pharmacist before you

buy them

- a group of medicines for your heart or blood pressure called ACE inhibitors such as ramipril or lisinopril or angiotensin II receptor antagonists such as losartan or irbesartan
- diuretics (water tablets), including herbal preparations
- steroids - used for inflammation and allergies (such as prednisolone, betamethasone or hydrocortisone).

These medicines may **decrease** the amount of lithium in your body meaning it will not work as well:

- theophylline (for asthma), or caffeine
- anything containing sodium bicarbonate
- a special group of diuretics (water tablets) called carbonic anhydrase inhibitors
- urea – used to treat skin conditions.

These medicines may cause other side effects when taken with LITHIUM CARBONATE:

- medicines used to treat schizophrenia such as haloperidol, olanzapine or clozapine
- carbamazepine, phenytoin or clonazepam used for epilepsy
- methyl dopa used for the treatment of high blood pressure
- anti-depressants called selective serotonin reuptake inhibitors (SSRIs) e.g. fluoxetine or paroxetine, or tricyclics e.g. amitriptyline or tetracyclics

- calcium channel blockers for angina, high blood pressure or other heart problems such as amlodipine or diltiazem
- muscle relaxants used in anaesthesia
- non-steroidal anti-inflammatory drugs such as indomethacin used to reduce pain and inflammation
- triptans such as sumatriptan used for migraine.

Some medicines when taken with LITHIUM CARBONATE can cause **serious** heart rhythm disorders. These include:

- quinidine, procainamide, disopyramide, amiodarone, ajmaline, cibenzoline, hydroquinidine, azimilide, dofetilide, ibutilide and sotalol all for heart rhythm disorders
- ranolazine for heart disease (angina)
- arsenic trioxide for the treatment of leukaemia
- erythromycin (given into a vein) and sparfloxacin for the treatment of infections
- amisulpride, haloperidol, pimozide, sertindole, mesoridazine, clozaril, droperidol and thioridazine for schizophrenia and other behavioural disorders
- terfenadine and astemizole (antihistamines)
- cisapride used to treat stomach and gut problems
- mefloquine, artemisinin derivatives and halofantrine used to prevent malaria
- ketanserin which may be being used for



- high blood pressure
- dolasetron which may be being used for nausea (feeling sick) and vomiting (being sick) following chemotherapy.

LITHIUM CARBONATE with food and drink

It does not matter if you take LITHIUM CARBONATE with or without food but if you want to go on any sort of diet talk to your doctor first. Any large changes in how much water you drink or how much sodium (salt) is in your diet may mean you need your blood monitoring more often.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

Do not take LITHIUM CARBONATE if you are pregnant or plan to become pregnant unless otherwise recommended by your doctor.

Breast-feeding

Do not take LITHIUM CARBONATE whilst breast-feeding.

Driving and using machines

As LITHIUM CARBONATE may cause dizziness or other nervous disorders, your ability to drive or use machines may be impaired.

LITHIUM CARBONATE contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE LITHIUM CARBONATE

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

When starting LITHIUM CARBONATE 400 mg tablets are usually taken twice a day but when your blood tests are stable you may be able to take it once a day.

Your doctor will give you a blood test to tell you how many tablets to take and when to take them. Your doctor will repeat the blood test regularly whilst you are taking LITHIUM CARBONATE.

Try to take your tablets at the same times every day. Use in children
LITHIUM CARBONATE should not be used in children.

If you take more LITHIUM CARBONATE than you should

Contact a doctor or the nearest hospital **immediately** if you take more LITHIUM CARBONATE than you should.

Signs of taking too much LITHIUM CARBONATE include abdominal pain, loss of appetite and nausea, sickness, diarrhoea, blurred vision, passing a lot of water, light-headedness, 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.

Tell your family about lithium side effects so they know what to look for too. If you forget

to take LITHIUM CARBONATE

If you forget to take LITHIUM CARBONATE, take it as soon as you remember. If you forget for more than 6 hours, just take the next dose when it is due. Tell your doctor if you forget a few doses. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor immediately if you:

- notice any changes in heart rate, for example a slower, faster or irregular heartbeat
- have a high fever, agitation, confusion, trembling, and abrupt contractions of muscles, these may be signs of a rare condition called serotonin syndrome
- experience a high temperature with rigid muscles, confusion or agitation, and sweating, or jerky muscle movements which you can't control, these may be symptoms of a serious condition known as neuroleptic malignant syndrome
- Experience persistent headaches and or visual disturbances.

Other side effects include:

- heart rhythm problems including a fast or irregular heartbeat and abnormal heart muscle function. Tests on your heart may show changes in the way your heart is working
- encephalopathy (alteration of brain function)
- syndrome of irreversible lithium effectuated neurotoxicity (permanent nerve tissue damage)
- kidney problems, which may not be reversible. Symptoms may include passing a lot of urine, or feeling thirsty and swollen ankles
- benign/malignant kidney tumours (microcysts, oncocytoma or collecting duct renal carcinoma) (in long-term therapy)
- parkinsonism (a condition characterised by tremor, slow body movements, rigid muscles, inability to stand steady, tendency to stoop, and a shuffling walk)
- thyroid problem and a condition known as parathyroid adenoma (a non-cancerous tumour close to the thyroid gland in the neck that controls the use and removal of calcium)
- oedema (usually seen as swelling caused by too much fluid)
- weight gain, loss of appetite or too much calcium, magnesium or sugar in the blood

hand tremor, vertigo, dazed feeling, not being able to think clearly, difficulty remembering, fits, changes of the sense of

taste, shaky movements, slurred speech, dizziness, rapid eye movements, blurred vision, or blind spots in your eyesight, unconsciousness, coma and myasthenia gravis (a long-term disease characterised by abnormal tiredness and muscle weakness)

- skin problems including worsening of psoriasis, hair loss, acne, soreness around the hair root, itching rashes and redness of the skin
- low blood pressure
- blood tests can show an increase in white blood cells (leucocytosis)
- sickness, feeling sick, diarrhoea, upset stomach, dry mouth or too much saliva
- sexual problems including being unable to get an erection, having delayed ejaculation or being unable to have an orgasm
- Abnormal taste sensation.

It is important to have the right level of lithium in the blood. If it is too high, then you are more likely to get a side effect.

Tell your family about lithium side effects so they know what to look for too.
Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE LITHIUM CARBONATE

Keep this medicine out of the sight and reach

of children. Do not store above 25°C. Keep the container tightly closed.

Do not use this medicine after the expiry date which is stated on the bottle label and on the carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION WHAT LITHIUM CARBONATE CONTAINS

a) Each tablet contains:
Lithium carbonate USP 300mg
Excipients q.s.

b) Each tablet contains:
Lithium carbonate USP 400mg
Excipients q.s.

c) Each tablet contains:
Lithium carbonate USP 450mg
Excipients q.s.

The other ingredients are maize starch, acacia, magnesium stearate, sodium laurilsulfate (see section 2 "LITHIUM CARBONATE contains sodium"), hypromellose, macrogol 400 and Opaspray.

What LITHIUM CARBONATE looks like and contents of the pack
PVC/PVDC/Al blisters.



Pack sizes: Blisters: 7, 14, 28, 30, 50, 90, 100 and 500 tablets.

Not all pack sizes may be marketed.

7. MANUFACTURED IN INDIA BY:

TAJ PHARMACEUTICALS LTD.

Mumbai, India

Unit No. 214.Old Bake House,

Maharashtra chambers of Commerce Lane,

Fort, Mumbai - 400001

at:Gujarat, INDIA.

Customer Service and Product Inquiries:

1-800-TRY-FIRST (1-800-222-434 & 1-800-222-825)

Monday through Saturday 9:00 a.m. to 7:00

p.m. EST

E-mail: tajgroup@tajpharma.com