Package leaflet: Information for the user

Lithium Carbonate Essential Pharma 250 mg film-coated tablets

Lit250mgTab-PL-UK-7

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.

Throughout this leaflet Lithium Carbonate Essential Pharma 250 mg film-coated tablets will be referred to as "Lithium Carbonate tablets".

What is in this leaflet

1. What Lithium Carbonate tablets are and what they are used for
2. What you need to know before you take Lithium Carbonate tablets
3. How to take Lithium Carbonate tablets
4. Possible side effects
5. How to store Lithium Carbonate tablets
6. Contents of the pack and other information.

1. What Lithium Carbonate tablets are and what they are used for

Lithium Carbonate 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 tablets

Do not take Lithium Carbonate tablets:

- 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 tablets:

- 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.
- if 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 a condition called Brugada syndrome (a hereditary syndrome that affects the heart), or if anyone in your family has had Brugada syndrome, heart arrest or sudden death.

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 tablets

Before you start taking Lithium Carbonate tablets, and while you are taking it, your doctor should check on your:

- 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 tablets. 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 tablets

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
- Topiramate (used to treat epilepsy or migraine)
- 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
- empagliflozin (used to treat diabetes or heart failure)
- dapagliflozin (used to treat diabetes or heart failure or chronic kidney disease).

These medicines may cause other side effects when taken with Lithium Carbonate tablets:

- medicines used to treat schizophrenia such as haloperidol, olanzapine or clozapine
- carbamazepine, phenytoin or clonazepam used for epilepsy
- methyldopa 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 tablets 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 tablets with food and drink

It does not matter if you take Lithium Carbonate tablets 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 tablets if you are pregnant or plan to become pregnant unless otherwise recommended by your doctor.
Breast-feeding
Do not take Lithium Carbonate tablets whilst breast-feeding.
Driving and using machines
As Lithium Carbonate tablets may cause dizziness or other nervous disorders, your ability to drive or use machines may be impaired.

3. How to take Lithium Carbonate tablets

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 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 tablets.

Try to take your tablets at the same times every day.
Use in children
Lithium Carbonate tablets should not be used in children.
If you take more Lithium Carbonate tablets than you should
Contact a doctor or the nearest hospital **immediately** if you take more Lithium Carbonate tablets than you should.
Signs of taking too much Lithium Carbonate tablets 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 tablets
If you forget to take Lithium Carbonate tablets take them 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.
- experience abnormal muscle breakdown (rhabdomyolysis) which can lead to kidney problems.
- experience serious disturbance in mental abilities that results in confused thinking and reduced awareness of the environment.

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
- frequency, very frequent: too much calcium in your blood
- frequency not known:
  - Unmasking and/or aggravation of Brugada Syndrome (a hereditary syndrome that affects the heart)
  - Hyperparathyroidism (when the parathyroid glands produce too much parathyroid hormone, which raises calcium levels in the blood).
  - Increased size of the parathyroid glands.
  - Parathyroid adenoma (a non-cancerous tumour).
  - Eruption of the skin or mucous membranes (lichenoid drug reaction)
  - Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome). Stop using Lithium Carbonate tablets if you develop these symptoms and contact your doctor or seek medical attention immediately.

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. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lithium Carbonate tablets

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.

6. Contents of the pack and other information

What Lithium Carbonate tablets contain
The active substance is lithium carbonate. Each tablet contains 250 mg lithium carbonate.
The other ingredients are maize starch, magnesium stearate, pregelatinised maize starch, hypromellose and macrogol 400.
What Lithium Carbonate tablets look like and contents of the pack
Each bottle contains 100 or 1000 white film-coated tablets.
Not all pack sizes may be marketed.
Lithium Carbonate tablets 250 mg are white film-coated tablets with CAMCOLIT on one face and a score-line on the other side.
Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Essential Pharma Ltd, 8a Crabtree Road, Egham, Surrey, TW20 8RN, UK.
Manufacturer
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