

Label

Camcolit[®] 250 mg

Lithium Carbonate

100 film-coated tablets

Each tablet contains 250 mg Lithium Carbonate

To be taken orally as directed by the doctor. Please read the pack leaflet.

Do not store above 25°C.

Keep container tightly closed.

Keep out of the reach and sight of children

EP logo

Essential Pharma (M) Limited, Birkirkara, BKR 9037, Malta

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Leaflet

PACKAGE LEAFLET: INFORMATION FOR THE USER CAMCOLIT 250 mg film-coated tablets Lithium Carbonate

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What CAMCOLIT is and what it is used for
2. Before you take CAMCOLIT
3. How to take CAMCOLIT
4. Possible side effects

- 5. How to store CAMCOLIT
- 6. Further information

1. What CAMCOLIT is and what it is used for

CAMCOLIT 250 mg tablets contain lithium carbonate, which is used to treat and prevent mania or manic depressive illness and recurrent depression. It is sometimes used to treat other behavioural disorders.

2. Before you take CAMCOLIT

Do not take CAMCOLIT if you:

- are hypersensitive (allergic) to lithium or to any of the other ingredients.
- have serious kidney disease.
- have hypothyroidism (low thyroid hormones) that is difficult to treat.
- have problems with the rhythm of your heart.
- have a condition called Brugada syndrome (a hereditary syndrome that affects the heart), or if anyone in your family has had Brugada syndrome.
- 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.
- are breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist if you:

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

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 CAMCOLIT

Before you start taking CAMCOLIT, and while you are taking it, your doctor should check on you:

- 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 CAMCOLIT. 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.

Taking 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
- 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 CAMCOLIT

- 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 CAMCOLIT can cause **serious** heart rhythm disorders. These include:

- quinidine, procainamide, disopyramide, amiodarone, ajmaline, cibenzoline, hydroquinidine, azimilide, dofetilidem, ibutide, 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.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking CAMCOLIT with food and drink

It does not matter if you take CAMCOLIT 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

Do not take CAMCOLIT if you are pregnant or plan to become pregnant unless otherwise recommended by your doctor. **Do not** take CAMCOLIT whilst breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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

3. How to take CAMCOLIT

Always take CAMCOLIT exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- when starting CAMCOLIT 250 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 CAMCOLIT.

Try to take your tablets at the same times every day.

If you take more CAMCOLIT than you should, contact a doctor or the nearest hospital **immediately.**

Signs of taking too much CAMCOLIT 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 your 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 miss a few doses.

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

4. Possible side effects

Like all medicines, CAMCOLIT 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.
- 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 unknown:

- Benign/malignant kidney tumours (microcysts, oncocytoma or collecting duct renal carcinoma) (in long-term therapy).
- Eruption of the skin or mucous membranes (lichenoid drug reaction).

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.

If any of the side effects become serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store CAMCOLIT

Keep all medicines out of the reach and sight of children.

Do not store above 25°C.

Keep the container tightly closed.

Do not use CAMCOLIT after the expiry date which is printed or embossed on the bottle label as month/year.

The expiry date refers to the last day of the month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What CAMCOLIT contains

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 CAMCOLIT looks like & contents of the pack

Each bottle contains 100 or 1000 white tablets.

CAMCOLIT 250 mg are white film-coated tablets with CAMCOLIT on one face and a scoreline on the other side.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is Essential Pharma (M) Limited, Orange Point Building, Dun Karm Street, Birkirkara By-Pass, Birkirkara, BKR 9037, Malta.

It is made by Delpharm L'Aigle, Zone Industrielle No1, Route de Crulai, L'AIGLE, 61300, France.

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