

Camcolit® 250mg film-coated Tablets

(lithium carbonate)

Patient Information Leaflet

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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Your medicine is called Camcolit 250mg film-coated Tablets but will be referred to as Camcolit Tablets throughout the leaflet.

In this leaflet:

- 1 What Camcolit Tablets are and what they are used for
- 2 Before you take Camcolit Tablets
- 3 How to take Camcolit Tablets
- 4 Possible side effects
- 5 How to store Camcolit Tablets
- 6 Further information

1 What Camcolit Tablets are and what they are used for

Camcolit 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 Tablets

Do not take Camcolit Tablets 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 the heart
- * have a condition called Brugada syndrome (a hereditary syndrome that affects the heart), or if anyone in your family has 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.

Warning 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.

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, oncocyoma or collecting duct renal carcinoma).

Whilst you are taking Camcolit Tablets

Before you start taking Camcolit 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 Camcolit 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 Camcolit 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 Camcolit 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 **decreased** the amount of Camcolit 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 Camcolit Tablets

- * medicines used to treat schizophrenia such as haloperidol, olanzapine or clozapine
- * carbamazepine, phenytoin or clonazepam used for epilepsy
- * methyl dopa used for 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 Tablets can cause **serious** heart rhythm disorders.

These include:

- * quinidine, procainamide, disopyramide, amiodarone, ajmaline, cibenzoline, hydroquinidine, azimilide, dofetilidem, ibutide and sotalol all for the 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 treat 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 recently have taken any other medicines, including medicines obtained without a prescription.

Taking Camcolit Tablets with food and drink

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

Pregnancy and breast-feeding

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

Driving and using machines

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

Camcolit® 250mg film-coated Tablets

(lithium carbonate)

Patient Information Leaflet (continued)

3 How to take Camcolit Tablets

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

- * When starting Camcolit Tablets, 250mg 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 Tablets.

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

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

Signs of taking too much Camcolit 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 Camcolit Tablets 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 Tablets 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 muscle, these may be signs of a rare condition called serotonin syndrome
- * experience a high temperature with rigid muscles, confusion or agitation, a 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 oncocyoma 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 Camcolit 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.

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

5 How to store Camcolit Tablets

KEEP OUT THE SIGHT AND REACH OF CHILDREN.

Do not store above 25°C.

Keep the container tightly closed in order to protect from moisture.

Do not take Camcolit Tablets after the expiry date which is stated on the container label or carton. The expiry date refers to the last day of the month.

If your doctor tells you to stop taking this medicine, return any unused tablets to your pharmacist (chemist) for safe disposal. Only keep this medicine if your doctor tells you to.

If your medicine becomes discoloured or shows any other signs of deterioration consult your pharmacist who will tell you what to do.

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 Further information

What Camcolit Tablets contain:

Each tablet contains 250mg of lithium carbonate.

The other ingredients are: maize starch, magnesium stearate, pregelatinised maize starch, hypromellose and macrogol 400.

What Camcolit Tablets look like and contents of the pack

Camcolit Tablets are white, round, convex film-coated tablets engraved 'Camcolit' around one face and a score line on the reverse.

Each container contains 100 film-coated Tablets.

Manufacturer and Licence Holder

Manufactured by Norgine Ltd, Hengoed, Mid Glamorgan, CF82 8SJ, UK and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

If you have any questions or are not sure about anything, ask your doctor or pharmacist. They will have additional information about this medicine and will be able to advise you.

POM PL 15184/1661 Camcolit 250mg film-coated Tablets

Camcolit is a registered trademark of Essential Pharma Limited.

Revision date: 03/08/16

Blind or partially sighted?

Is this leaflet hard to see or read?

Phone Lexon (UK) Limited, Tel: 01527 505414 for help.

Lithium Carbonate Essential Pharma 250mg film-coated Tablets

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

Your medicine is called Lithium Carbonate Essential Pharma 250mg film-coated Tablets but will be referred to as Lithium Carbonate Tablets throughout the leaflet.

In this leaflet:

- 1 What Lithium Carbonate Tablets are and what they are used for
- 2 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 Further 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. It is sometimes used to treat other behavioural disorders.

2 Before you take Lithium Carbonate Tablets

Do not take Lithium Carbonate Tablets 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 the heart
- * have a condition called Brugada syndrome (a hereditary syndrome that affects the heart), or if anyone in your family has 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.

Warning and precautions

Talk to your doctor or pharmacist if you:

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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 Carbonate 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:

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- * 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
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- * mefloquine, artemisinin derivatives and halofantrine used to treat 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.

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Pregnancy and breast-feeding

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

Driving and using machines

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Lithium Carbonate Essential Pharma 250mg film-coated Tablets

Patient Information Leaflet (continued)

3 How to take Lithium Carbonate Tablets

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

- * When starting Lithium Carbonate Tablets, 250mg 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.

If you take more Lithium Carbonate Tablets than you should, contact a doctor or the nearest hospital immediately.

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.

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4 Possible side effects

Like all medicines, Lithium Carbonate Tablets can cause side effects, although not everybody gets them.

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- * have a high fever, agitation, confusion, trembling, and abrupt contractions of muscle, these may be signs of a rare condition called serotonin syndrome
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- * encephalopathy (alteration of brain function)
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