1.3.2.1 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

CAMCOLIT 250 mg film-coated tablets

CAMCOLIT 400 mg film-coated tablets

Lithium carbonate

Sugar free

Read all of this leaflet carefully before you start taking CAMCOLIT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- CAMCOLIT has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

5. How to store CAMCOLIT
6. Contents of the pack and other information

1. What CAMCOLIT is and what it is used for

CAMCOLIT belongs to a group of medicines called Central Nervous System Stimulants.

CAMCOLIT tablets contain lithium carbonate, which is used to treat and prevent relapse of mania or manic depressive illness.

2. What you need to know before you take CAMCOLIT

Do not take CAMCOLIT:

- if you are hypersensitive (allergic) to lithium or any of the other ingredients of CAMCOLIT (listed in section 6).
- if you have serious kidney disease or kidney failure.
- if you have problems with the rhythm of your heart or have a heart condition or heart failure.
- if you have low sodium levels in your body. This can happen if you are dehydrated, on a low sodium (salt) or salt-free 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, light-headed and areas of your skin may go darker.
- if you have evidence of brain damage.
- if you are are pregnant or breastfeeding.

- if you have a genetic condition where the heart's electrical activity takes longer to complete its cycle, leading to a higher risk of dangerous, irregular heartbeats (congenital long QT syndrome).
- if you are using medicines that change the heart rhythm.

Warnings and precautions

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

- Kidneys and urine
- Thyroid
- Heart

At the beginning of CAMCOLIT therapy, your doctor will monitor the level of lithium in your blood and adjust your dose accordingly. Your doctor will suggest that you have regular blood tests in order to ensure that your CAMCOLIT dose is correct.

CAMCOLIT must be discontinued 24 hours before any surgery.

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.

Seek urgent medical attention if you notice any of the following: increased urination (polyuria), increased thirst (polydipsia), nausea and vomiting.

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

Take special care with CAMCOLIT:

- if there is a change in your dose or you change brands of lithium tablets.
- if you have epilepsy and take medicines to treat it.
- if you develop persistent headaches and or visual disturbance (benign intracranial hypertension).
- if you have heart disease (including Brugada syndrome) or heart rate problems (including QT prolongation).
- if you have low amounts of potassium, magnesium and calcium in your blood - your doctor will tell you this.
- if you take antipsychotic medications, which include olanzapine and clozapine.
- 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 kidney disease that you have been told by your doctor is not serious.
- if you have a thyroid problem.
- if there are large changes in the amount of fluid you drink or sodium (salt) you consume.
- if you are planning to have major surgery, CAMCOLIT should be stopped 24 hours before the procedure.
- if you have an infection or other existing disease/disorder.
- blood tests may show raised levels of antidiuretic hormone while using CAMCOLIT.

- if you are taking other medicines e.g. non-steroidal anti-inflammatory medicines of which some are available over the counter.

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).

Children and adolescents

Not recommended for use in children.

Other medicines and CAMCOLIT

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

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 such as metronidazole, tetracyclines, co-trimoxazole, trimethoprim and spectinomycin,
- non-steroidal anti-inflammatory medicines (e.g. diclofenac, ibuprofen, or celcoxib). 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,
- groups of medicines for your heart or blood pressure called ACE- inhibitors and ARB's (angiotensin receptor blockers),
- diuretics (water tablets),
- steroids - used for inflammation and allergies (such as prednisolone, betamethasone or hydrocortisone),

- topiramate, used to prevent seizures.

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 and chloride,
- acetazolamide (a medicine used for glaucoma, altitude sickness and epilepsy),
- 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 following medicines may cause other side effects when taken with CAMCOLIT:

- medicines used to treat psychotic disorders, such as olanzapine, clozapine, or haloperidol,
- medicines that act on the central nervous system may cause neurological damage (neurotoxicity),
- carbamazepine, phenytoin or clonazepam used for epilepsy,
- methyldopa used for the treatment of high blood pressure,
- antidepressants called selective serotonin reuptake inhibitors (SSRIs), or tricyclic antidepressants,
- calcium channel blockers for angina, diltiazem and verapamil for high blood pressure or other heart problems,
- muscle relaxants used in anaesthesia, as anaethetics can lower the seizure threshold,

- 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.

- quinidine, procainamide, disopyramide, amiodarone, ajmaline, cibenzoline, hydroquinidine, azimilide, dofetilide, ibutilide and sotalol, 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,
- cisapride used to treat stomach and gut problems,
- mefloquine, artemisinin derivatives and halofantrine used to prevent malaria,
- ketanserin which may be used for high blood pressure,
- dolasetron which may be used for nausea (feeling sick) and vomiting (being sick) following chemotherapy.

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, breastfeeding and fertility

You should not take CAMCOLIT if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Driving and using machines

Since adverse reactions such as blackout spells, confusion, dizziness and blurred vision have been reported in patients receiving CAMCOLIT, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that CAMCOLIT does not adversely affect your ability to do so (see section 4).

It is not always possible to predict to what extent CAMCOLIT may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which CAMCOLIT affects you (see section 4).

3. How to take CAMCOLIT

Do not share medicines prescribed for you with any other person.

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

When starting CAMCOLIT, tablets are taken either once or more often per 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, at least every 10 weeks, whilst you are taking CAMCOLIT.

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

Your doctor will tell you how long your treatment with CAMCOLIT will last. If you have the impression that the effect of CAMCOLIT is too strong or too weak, tell your doctor or pharmacist.

If you take more CAMCOLIT than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre immediately.

Signs of taking too much CAMCOLIT include abdominal pain, loss of appetite and nausea, vomiting, diarrhoea, blurred vision, passing a lot of water, difficulty controlling the bladder or bowel, light-headedness, restlessness, confusion, fainting, blackouts, tremor, muscle twitching, jerky movements, muscle weakness, lack of co-ordination, ringing in the ears, drowsiness. In extreme cases unconsciousness, rigid arms or legs, severe trembling, speech disturbances, metallic taste, extreme thirst (hypernatraemia), severe confusion, fits, dehydration, coma, deaths have been reported, very low or rarely, high blood pressure, heart rhythm changes, kidney and circulatory failure can occur.

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

If you forget to take CAMCOLIT

Take the dose that you have missed as soon as you remember. If more than 6 hours have lapsed, just take the next dose when it is due. Tell your doctor if you miss a few doses.

Do not take a double dose to make up for forgotten individual doses.

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

4. Possible side effects

CAMCOLIT can have side effects.

Not all side effects reported for CAMCOLIT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CAMCOLIT, please consult your healthcare provider for advice.

If any of the following happens, stop taking CAMCOLIT and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- skin rash with fever, swollen lymph nodes and face, dry cracked lips, sore throat and other symptoms due to a serious reaction called DRESS (Drug reaction with eosinophilia and systemic symptoms).

These are all very serious side effects. If you have them, you may have had a serious reaction to CAMCOLIT. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Cardiac arrest, weak heart muscle (cardiomyopathy), heart rhythm problems or changes in heart rate (symptoms of cardiac arrythmias or Brugada syndrome), including a slower, faster or irregular heartbeat and abnormal heart muscle function. Tests on your heart may show changes in the way your heart is working,

- have a high fever, agitation, confusion, trembling, and abrupt contractions of muscles as these may be signs of a rare condition called serotonin syndrome,
- blood tests can show an increase in white blood cells (leucocytosis) and antibodies,
- 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,
- persistent headaches and or visual disturbances (symptoms of benign intracranial hypertension),
- abnormal muscle breakdown (rhabdomyolysis) which can lead to kidney problems,
- serious disturbance in mental abilities that results in confused thinking and reduced awareness of the environment (delirium),
- kidney problems such as nephrotic syndrome which may not be reversible. Symptoms may include passing a lot of urine, feeling thirsty and swollen ankles,
- diabetes insipidus (with excessive thirst),
- encephalopathy (alteration of brain function),
- parkinsonism (a condition characterised by tremor, slow body movements, rigid muscles, inability to stand steady, tendency to stoop, and a shuffling walk),
- fainting (syncope), loss of muscle co-ordination or difficulty controlling movements (ataxia), a muscle disorder causing weakness (myasthenia gravis), a state of prolonged unconsciousness where a person is unable to be awakened by external stimuli (coma), syndrome of irreversible lithium effectuated neurotoxicity (SILENT), fits caused by sudden abnormal electrical discharges in the brain (epileptiform seizures),
- benign/malignant kidney tumours (microcysts, oncocytoma or collecting duct renal carcinoma) which can occur in long term treatment,

- a non-cancerous (benign) tumour of one of the parathyroid glands (parathyroid adenoma),
- allergic vasculitis (swelling of the blood vessels), narrowed or blocked blood vessels reducing blood flow to the limbs (peripheral circulatory collapse), oedema (usually seen as swelling caused by too much fluid),
- sudden unexplained death.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Weight gain, or too much calcium in the blood (hypercalcaemia),
- sickness, feeling sick (nausea), diarrhoea, upset stomach,
- excessive thirst (polydipsia),
- hand tremor.

Less frequent side effects:

- Blurred vision or blind spots in your eyesight, involuntary, rapid movement in one or both eyes (nystagmus),
- headache, fainting, not being able to think clearly,
- thyroid problems (hypothyroidism or hyperthyroidism),
- muscle weakness, twitching, rigidity, or hyperirritability as well as shaky movements and lack of coordination,
- a state of near unconsciousness or insensibility (stupor) or confusion,
- changes of the sense of taste, slurred speech, dizziness,
- occurrence or worsening of acne,

- protein in the urine (albuminuria).

Side effects with an unknown frequency:

- Giddiness, vertigo, restlessness, dazed feeling, sleepiness, decrease in memory,
- abnormal patterns in the electrical activity of the brain seen on electroencephalogram (EEG),
- vomiting, dry mouth or too much saliva, abnormal taste (dysgeusia),
- magnesium or sugar in the blood,
- difficulty controlling passing of urine and faeces,
- loss of appetite (anorexia), too much magnesium or sugar in the blood,
- fatigue, drowsiness, lack of energy, feeling unwell (malaise), ringing in the ears,
- change in blood pressure (such as low blood pressure (hypotension) or high blood pressure (hypertension)),
- protrusion of eyes (which can be associated with a goitre), excess thyroid hormone in the body (thyrotoxicosis),
- a condition where one or more of the parathyroid glands produce too much parathyroid hormone (hyperparathyroidism) or an enlarged parathyroid gland (parathyroid hyperplasia),
- increase in antinuclear antibodies,
- eruption of the skin or mucous membranes (lichenoid drug reaction), skin problems including worsening of psoriasis, hair loss, acne, itching, rashes, and redness of the skin,
- sexual problems,
- inflammation of the stomach (gastritis),

- large amounts of glucose in the urine (glycosuria) or passing a large amount of urine (polyurea),
- an abnormal lack of energy (lethargy) or generalised weakness (asthenia).

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.

If any of the above become serious or last more than a few days or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/+27 (0)11 239-6200

By reporting side effects, you can help provide more information on the safety of CAMCOLIT.

5. How to store CAMCOLIT

Store all medicines out of reach of children.

Store in a cool, dry place, at or below 25 °C.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CAMCOLIT contains

CAMCOLIT 250: The active substance is 250 mg lithium carbonate.

The other ingredients are hydroxypropyl methyl cellulose (hypromellose), macrogol 400, magnesium stearate, maize starch, pregelatinized maize starch.

Sugar free

CAMCOLIT 400: The active substance is 400 mg lithium carbonate.

The other ingredients are acacia, hydroxypropyl methyl cellulose (hypromellose), macrogol 400, magnesium stearate, maize starch, methylated ethyl alcohol, sodium laurilsulfate, titanium dioxide.

Sugar free

What CAMCOLIT looks like and contents of the pack

CAMCOLIT 250 is a white, film-coated convex tablets, engraved “Camcolit” around one face of the tablet and a breakline on the reverse.

CAMCOLIT 400 is a white, film-coated convex tablets, with a breakline on one side and “Camcolit S” engraved on the other side.

CAMCOLIT 250:

100 and 1 000 tablets are packed in a snap secure white polypropylene container, with a snap secure white polyethylene cap and a white polyethylene Jayfilla wad.

100 tablets are packed in a white polypropylene securitainer with a white LLDPE closure.

CAMCOLIT 400:

100 and 500 tablets are packed in a snap secure white polypropylene container, with a snap secure white polyethylene cap and a white polyethylene Jayfilla wad.

100 tablets are packed in a white polypropylene securitainer with a white LLDPE closure.

Not all packs or pack sizes may be marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912/+27 (0)11 239-6200

This leaflet was last revised in

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Registration numbers

CAMCOLIT 250: B1260 (Act 101/1965)

CAMCOLIT 400: L/1.2/0161

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Botswana:	S2
Camcolit 250:	BOT1001689
Camcolit 400:	BOT1001690

Namibia:	NS3
Camcolit 250:	05/1.2/0440
Camcolit 400:	90/1.2/00671

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