

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S5**

PROPRIETARY NAME AND DOSAGE FORM

CAMCOLIT 250

Film-coated Tablets

CAMCOLIT 400

Film-coated Tablets

Read all of this leaflet carefully before you start CAMCOLIT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- 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 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, pregelatinised 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, Opaspray, sodium lauryl sulphate.

Sugar free

WHAT CAMCOLIT IS USED FOR

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

BEFORE TAKING CAMCOLIT

Do not take CAMCOLIT if you

- are hypersensitive (allergic) to lithium or to any of the other ingredients in CAMCOLIT
- have serious kidney disease
- have hypothyroidism (low thyroid hormones) that is difficult to treat
- have problems with the rhythm of your heart or have a heart condition
- 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
- have evidence of brain damage
- are pregnant or breastfeeding

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

- Kidneys and urine
- Thyroid

- Heart

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

Take special care with CAMCOLIT

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 e.g. non-steroidal anti-inflammatory medicines of which some are available over the counter
- You have kidney disease that you have been told by your doctor is not serious.

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 breastfeeding

Do not take CAMCOLIT if you are pregnant or plan to become pregnant unless otherwise recommended by your doctor. **Do not** take CAMCOLIT whilst breastfeeding.

Always tell your healthcare provider if you are taking any other medicine. If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking CAMCOLIT.

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 POSSIBLE SIDE EFFECTS).

Taking other medicines with CAMCOLIT

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

Tell your doctor if you are taking any of the following medicines:

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.
- An antibiotic called metronidazole.
- Non-steroidal anti-inflammatory drugs. 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).

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).

These following medicines may cause other side effects when taken with CAMCOLIT:

- Medicines used to treat psychotic disorders
- 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
- Diltiazem and verapamil for high blood pressure or other heart problems

Some medicines when taken with CAMCOLIT can cause **serious** heart rhythm disorders.

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

HOW TO TAKE CAMCOLIT

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

Always take CAMCOLIT exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

- When starting CAMCOLIT, tablets are 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 overdose, 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, confusion, tremor, muscle twitching, 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, severe confusion, fits, dehydration, coma, deaths have been reported, very low or rarely, high blood pressure, 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 it 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.

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

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 doctor, pharmacist or other 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:

- 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 as 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.

These are all very serious side effects. 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:

- 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;
- kidney problems which may not be reversible. Symptoms may include passing a lot of urine, feeling thirsty and swollen ankles;
- difficulty controlling passing of urine and faeces;
- thyroid problems;
- 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, restlessness, dazed feeling, fainting, not being able to think clearly, seizures, muscle rigidity, changes of the sense of taste, shaky movements, lack of co-ordination, slurred speech, dizziness, rapid eye movements, blurred vision, protrusion of eyes 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, itching, rashes, and redness of the skin;
- change in blood pressure;
- blood tests can show an increase in white blood cells (leucocytosis) and antibodies;
- diabetes insipidus (with excessive thirst).

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

Tell your doctor if you notice any of the following:

- Sickness, feeling sick, diarrhoea, upset stomach, vomiting, dry mouth or too much saliva;
- fatigue, muscle weakness, drowsiness, ringing in the ears;

- headache.

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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORAGE AND DISPOSING OF CAMCOLIT

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

Keep in original packaging until required for use.

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).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF CAMCOLIT

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.

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.

Not all packs and pack sizes are necessarily marketed.

IDENTIFICATION OF CAMCOLIT

CAMCOLIT 250: White, film-coated convex tablets, engraved "CAMCOLIT" around one face of tablet and breakline on the reverse.

CAMCOLIT 400: White, film-coated convex tablets, with a breakline on one side and "CAMCOLIT S" engraved on the other side.

REGISTRATION/REFERENCE NUMBER

CAMCOLIT 250: B1260 (Act 101/1965)

CAMCOLIT 400: L/1.2/0161

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Tel: 0800 122 912

DATE OF PUBLICATION

Date of registration:

CAMCOLIT 250: Old Medicine

CAMCOLIT 400: 09 August 1982

Date of the most recent amendment to the patient information leaflet as approved by the authority: 20 April 2012

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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