

- a speech disorder, confusion, impaired consciousness or loss of consciousness
 - loss of appetite, diarrhoea, vomiting, muscle weakness, difficulty in co-ordinating movements, drowsiness, tiredness, dizziness, ringing in your ears, blurred vision, slurred speech, muscle twitching and shaking or fits. The amount of lithium in your blood may be too high
 - altered mental state due to brain disease, damage or malfunction (encephalopathy)
 - difficulty in walking or unusual movements such as involuntary eye movements
 - abnormal muscle breakdown (rhabdomyolysis) which can lead to kidney problems.
- If any of the above applies to you, stop taking this medicine and contact your doctor or hospital casualty department straight away. This is especially important if you are an older person.**

Tell your doctor as soon as possible if you get any of the following:

- changes in heart rate. The most common is a slow heart beat and low blood pressure
- change in thyroid function. This may show as underactive (feeling very tired and slow, sweaty, shaky and unable to tolerate heat) or overactive (bone pain or tenderness, tiredness and vomiting). You may also notice a swelling in the neck.

Tell your doctor if you get any of these side effects:

- shaking of your hands
- passing more water (urine) than normal or feeling thirsty
- loss of appetite with a strange taste in your mouth, feeling sick (nausea) or being sick (vomiting), diarrhoea, a dry mouth or producing too much saliva, stomach pain and swelling of the stomach lining
- increase in weight, water retention and swelling (particularly the feet and ankles)
- feeling dizzy, feeling very tired, feeling less alert or dazed, forgetful
- severe headache, blurred vision or blind spots in your eyesight and rapid uncontrollable eye movements
- numbness, tingling and colour change (white, blue then red) in your fingers and toes when exposed to the cold
- hair loss, acne, skin rash, psoriasis or worsening of psoriasis and leg ulcers
- sexual problems.

Tests

A change in blood tests may occur, particularly high white blood cell counts, high blood sugar levels, and high magnesium or calcium levels. Your doctor will notice this when you have your blood tests.

A test on your heart may show changes in the way your heart is working.

Lithium taken for a long time can cause kidney damage. This can usually be avoided if your kidney function is tested regularly by your doctor. Drinking plenty of fluids while taking this medicine will also help avoid kidney damage.

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

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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 Li-Liquid

- Keep out of the sight and reach of children
- Store above 4°C and keep out of direct sunlight
- Do not use after the expiry date which is stated on the label and carton. (exp: month, year)
- The expiry date refers to the last day of that month
- Do not use Li-Liquid if you notice that the appearance or smell of your medicine has changed. Talk to your pharmacist
- Medicines should not be disposed of via wastewater or household waste. Take back to the pharmacy 6 months after you first open it. These measures will help to protect the environment.

6. Contents of the pack and other information

What Li-Liquid contains

- The active ingredient is lithium citrate. Each 5ml contains 509mg of lithium citrate. This is the same as 200mg lithium carbonate
- The other ingredients are citric acid (E330), saccharin sodium, sorbitol solution (E420), syrup liquid glucose, propylene glycol (E1520), methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), colouring E104, cherry flavour (containing ethanol and propylene glycol) and purified water.

What Li-Liquid looks like and contents of the pack

A bright yellow syrup with an odour of cherry.
It comes in a brown glass bottle holding 150ml of syrup.

Marketing Authorisation Holder and Manufacturer

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

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Patient Information Leaflet

Li-Liquid™ 509mg/5ml Oral Syrup

Lithium Citrate (equivalent to 200mg/5ml Lithium Carbonate)

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.

What is in this leaflet

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| 1. What Li-Liquid is and what it is used for | 4. Possible side effects |
| 2. What you need to know before you take Li-Liquid | 5. How to store Li-Liquid |
| 3. How to take Li-Liquid | 6. Contents of the pack and other information |

1. What Li-Liquid is and what it is used for

The name of your medicine is Li-Liquid 509mg/5ml Oral Syrup (referred to as Li-Liquid in this leaflet). It contains lithium citrate. This belongs to a group of medicines called 'anti-manics'.

Lithium acts on the brain to calm your moods and emotions.

Lithium can be used to:

- treat mania (over-excitability and exaggerated emotions) and hypomania (a milder form of mania)
- treat bipolar depression. This is a condition where you have large mood swings from low mood and feelings of sadness (depression), to feeling excited and overactive. Lithium will be given when other antidepressant drugs have not worked
- prevent mood problems that happen a lot
- control aggressive feelings or if you have been intentionally harming yourself.

2. What you need to know before you take Li-Liquid

Do not take Li-Liquid and tell your doctor if:

- you are allergic (hypersensitive) to lithium or any other ingredients in this liquid (listed in section 6). The signs of allergic reaction can include a rash, swelling of your lips, face, throat or tongue, itching or shortness of breath
- you have kidney problems or heart disease
- you have thyroid problems that are not being treated. The signs of these include tiredness, feeling weak, muscle weakness, cramps, feeling cold, a slow heart rate, dry and flaky skin, hair loss, a deep husky voice or weight gain
- you are on a low sodium diet or have low body sodium levels, including being dehydrated
- you have Addison's disease. This is where your adrenal glands are not working properly. The signs of this are weakness, tiredness, weight loss and low blood pressure
- you are pregnant, think you are pregnant or breast-feeding
- you have a rare condition called Brugada syndrome, or if anyone in your family has had Brugada syndrome. This is an abnormal condition of the heart that can make it stop beating.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Li-Liquid.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if:

- you currently have an infection
- you have gastroenteritis. This is when you have a problem with your stomach or gut. Signs include diarrhoea, stomach pain, being sick, headache, fever and you have any urinary problems such as infections
- you are elderly
- you are not eating or drinking properly
- you have kidney problems
- you are taking medicines to treat epilepsy
- you have heart problems.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Li-Liquid.

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).

Continued overleaf

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Having operations and tests

- if you are going into hospital for an operation under general anaesthetic, tell the nurse or doctor that you are taking lithium
- it is important to have blood tests before and whilst taking Li-Liquid. These show that you are taking the right dose. They also check whether your heart, thyroid and kidneys are working properly (see Section 3).

Other medicines and Li-Liquid:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Li-Liquid can affect the way some other medicines work.

Also, some medicines can affect the way Li-Liquid works as this can affect the levels of lithium in your blood.

In particular, check with your doctor if you are taking any of the following:

- Any other medicines containing lithium
- Medicines used for infections (antibiotics) - such as metronidazole, erythromycin, doxycycline or oxytetracycline
- Steroids - used for inflammation and allergies (such as prednisolone, betamethasone or hydrocortisone)
- Theophylline - used for wheezing or difficulty in breathing
- Caffeine found in some medicines for pain relief that you buy without a prescription
- Water tablets (diuretics) - such as furosemide, chlortalidone, indapamide, spironolactone or xipamide
- Urea - used in some creams that soften and moisturise the skin
- Non-steroidal anti-inflammatory drugs (NSAIDs) - used to treat pain relief and swelling (such as aspirin, ibuprofen, indomethacin or diclofenac)
- Medicines used for heart problems or high blood pressure – such as enalapril, lisinopril or ramipril (ACE inhibitors)
- Medicines used to control your heart beat – such as quinidine, disopyramide, procainamide, amiodarone and sotalol
- Losartan candesartan, irbesartan (called 'angiotensin II receptor antagonists')
- Some medicines for indigestion and heartburn (antacids) - such as sodium bicarbonate and cisapride
- Calcitonin – used for hypercalcaemia and Paget's disease/acute bone loss.

The following medicines can increase the chance of side effects when taken with Li-Liquid. Tell your doctor if you are taking any of the following before taking Li-Liquid:

- Some medicines used for depression (SSRIs), tricyclics and triptans derivatives - such as fluvoxamine, paroxetine or fluoxetine
- Medicines used to calm emotional and mental illnesses - such as haloperidol, flupentixol, diazepam, thioridazine, amisulpride, fluphenazine, chlorpromazine or clozapine. Coadministration with Li-Liquid may increase the risk of a serious but rare side effect called 'neuroleptic malignant syndrome', which may be fatal
- Methyldopa used for high blood pressure
- Some medicines used for fits (epilepsy) - such as carbamazepine or phenytoin
- Medicines used for chest pain (angina) or high blood pressure - such as diltiazem or verapamil.

Li-Liquid with food and drink

It is important that you drink plenty of fluids whilst taking this medicine particularly in very hot weather or if your workplace is very hot.

Pregnancy and Breast-feeding:

Information for women who could become pregnant

- if you are planning to become pregnant, talk to your doctor about stopping the medicine
- you should make sure that you use adequate contraception whilst taking lithium

Information for women who are pregnant

- if you find out you are pregnant while taking Li-Liquid, tell your doctor straight away
- do not take Li-Liquid if you are pregnant, especially in the first 3 months of your pregnancy

If your doctor decides that you should have Li-Liquid while you are pregnant, he or she will:

- keep a close eye on the level of lithium in your blood. This is because your kidneys work differently while you are pregnant
- arrange for appropriate tests before your baby is born.

If it is decided you should have Li-Liquid during late pregnancy or during labour, your baby may appear 'floppy'. This returns to normal without any treatment.

Breast-feeding

- do not take this medicine if you are breastfeeding. This is because small amounts may pass into the mother's milk

Driving and using machines:

This medicine may slow down your reactions or make you feel drowsy. If this happens to you, you should not drive or use any tools or machines.

Li-Liquid contains methyl parahydroxybenzoate, propyl parahydroxybenzoate, glucose, sorbitol and ethanol:

- Methyl and propyl hydroxybenzoates (E218 and E216). These may cause an allergic reaction. This allergy may happen some time after starting the medicine

- Glucose and sorbitol (E420). If your doctor has told you that you cannot tolerate some sugars, see your doctor before taking this medicine. It contains 1.7g of glucose in each 5ml. When taken according to dosage recommendations, the maximum dose supplies up to 10.2g of glucose. This should be taken into account in patients with diabetes mellitus and may be harmful to teeth
- Ethanol (alcohol). This product contains a small amount of alcohol, less than 100mg per dose.

3. How to take Li-Liquid

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

Taking this medicine

- this medicine contains 509mg of lithium citrate in each 5ml. This is the same as 200mg lithium carbonate
- take this medicine by mouth
- if you feel that the effect of your medicine is too strong or too weak, do not change the dose yourself, but talk to your doctor or pharmacist
- your doctor will check your blood levels while you are taking this medicine. These tests will be done just before you are due to take Li-Liquid and not less than 12 hours after your last dose. **It is important that you do not miss these tests.** The tests will be:
 - 4 to 5 days after you have started your treatment
 - then every week until your lithium levels are at a constant level in your blood
 - once the levels are stable, you will have this test every 3 months.

Thoughts of harming or killing yourself

If you have a mood disorder, you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting Li-Liquid or changing your dose of Li-Liquid. Like other medicines of this kind, Li-Liquid may not relieve your symptoms straight away. If you have thoughts of harming or killing yourself or worsening of your symptoms at any time, contact your doctor or go to a hospital straight away.

You may find it helpful to tell a relative, close friend or carer that you have a mood disorder, and ask them to read this leaflet. You might ask them to tell you if they think your mood disorder is getting worse, or if they are worried about changes in your behaviour.

Adults

The usual dose for adults is:

- when first taking lithium, two to six 5ml spoonful. This will be split into two doses, one in the morning and one in the evening.
- your doctor will then change your dose according to your blood levels.

Children

Lithium is not recommended for children and adolescents.

Older people

If you are an older person you may be more sensitive to the medicine. This means you have more of a chance of getting some of the side effects listed in section 4. Your doctor will start you on a lower dose.

If you take more Li-Liquid than you should

Talk to a doctor or go to a hospital straight away. Take the medicine pack with you so the doctor knows what you have taken.

If you forget to take Li-Liquid

Do not take a double dose (two doses at the same time) to make up for forgotten doses. Skip the missed dose then go on as before.

If you stop taking Li-Liquid

Keep taking Li-Liquid until your doctor tells you to stop. Do not stop taking your medicine suddenly just because you feel better. If you stop, your illness may return. When your doctor says that you can stop taking Li-Liquid, your dose will be lowered gradually. Your doctor will help you to do this.

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

4. Possible side effects

Like all medicines, lithium can cause side effects, although not everybody gets them.

Stop taking the medicine and contact your doctor or hospital casualty department straight away if you get:

- an allergic reaction to Li-Liquid such as skin rash, flaking skin, boils or sore lips and mouth, sudden wheezing, fluttering or tightness of the chest or collapse
- irregular or slow heart beats
- high blood pressure, swollen hands and feet and swelling around the eyes, more infections than usual. These could be signs of a kidney problem called 'nephrotic syndrome'

Continued overleaf