PACKAGE LEAFLET:
INFORMATION FOR THE USER

Priadel 200 mg and 400 mg prolonged-release tablets
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

1. What Priadel tablets are and what they are used for
2. What you need to know before you take Priadel tablets
3. How to take Priadel tablets
4. Possible side effects
5. How to store Priadel tablets
6. Contents of the pack and other information

1. What Priadel tablets are and what they are used for

The name of your medicine is Priadel 200 mg or Priadel 400 mg prolonged-release tablets (called Priadel tablets in this leaflet). Priadel tablets contain a medicine called lithium. This belongs to a group of medicines called mood stabilisers. It works by stabilising the levels of chemicals in your brain that affect your mood.

Priadel tablets can be used to manage or control:
- Mania (feeling highly excited, being over-active and easily irritated or distracted).
- Hypo-mania (similar to mania, but less severe).
- Repeated periods of depression, where treatment with other medicines has not worked.
- Aggressive or self-harming behaviour.

It is also used to help prevent bipolar depression - where the mood changes between feeling very high (mania) and very low (depression).

2. What you need to know before you take Priadel tablets

Do not take Priadel tablets:
- if you are allergic to lithium carbonate or any of the other ingredients of this medicine (listed in Section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- if you are breast-feeding.
- if you have heart disease.
- if you have severe kidney problems.
- if you have an under-active thyroid gland that is not being treated.

- if you have low levels of sodium in your body. This can happen if you are dehydrated or on a low sodium diet.
- if you have an illness called 'Addison's disease'. This happens when your body does not produce enough hormones. This makes you feel tired, weak, light-headed and makes areas of your skin go darker.
- if you have a rare condition called Brugada syndrome (a hereditary syndrome that affects the heart), or if anyone in your family has had Brugada syndrome.

Warnings and precautions

Talk to your doctor or pharmacist before taking Priadel tablets if:
- You have a cold or flu.
- 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 chills.
- You have a urinary infection.
- 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.
- You are about to receive anaesthetics.
- 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.
- You have a condition called Brugada syndrome (a hereditary syndrome that affects the heart), or if anyone in your family has had Brugada syndrome, heart arrest or sudden death.

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).

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

Other medicines and Priadel tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Priadel tablets can affect the way some other medicines work. Also, some medicines can affect the way Priadel tablets work as this can affect the level 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.
- Topiramate (used to treat epilepsy or migraine).
- 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 acetazolamide.
- 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.
- Empagliflozin - used to treat diabetes or heart failure.
- Dapagliflozin – used to treat diabetes or heart failure or chronic kidney disease.

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

Priadel tablets with food and drink
Your diet and the amount of fluid you drink while taking Priadel tablets is very important (see Section 3 below 'Diet, food and drink while taking Priadel tablets').

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Information for women who could become pregnant
- Talk to your doctor before taking this medicine if you plan to get pregnant, or think you may be pregnant. It is very important that you talk to your doctor about your treatment well before you become pregnant.
- You should use an effective method of contraception while taking Priadel tablets.

Information for women who are pregnant
- If you find out you are pregnant while taking Priadel tablets, tell your doctor straight away.
- Do not take Priadel tablets if you are pregnant, especially in the first 3 months of your pregnancy.

If your doctor decides that you should have Priadel tablets 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 that you should have Priadel tablets during late pregnancy or during labour, your baby may appear 'floppy'. This returns to normal without any treatment.

Breast-feeding
- Do not breast-feed if you are taking Priadel tablets. This is because small amounts may pass into the mother's milk.

Driving and using machines
Do not drive or use any tools or machines if you feel sleepy, tired or dizzy. Priadel tablets may also cause other effects that can make it dangerous to drive or use tools and machines such as numbness, paralysis, weakness or fits (seizures).

Priadel tablets contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Priadel tablets

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

Diet, food and drink while taking Priadel tablets
The amount you eat and drink is very important as it can affect the levels of Priadel tablets in your blood.
- Drink the same amount of fluids every day while taking Priadel tablets. In hot environments or if you are dehydrated, you may need to drink extra fluids.
- Have a normal balanced diet while taking Priadel tablets. Do not change your diet without talking to your doctor first.

How to take your medicine
- Take this medicine by mouth.
- Swallow the prolonged-release tablets whole. Do not crush or chew them.
- The prolonged-release tablets can be broken in half.
- Take your medicine at the same times every day.
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

Adults weighing about 70 kg
- The usual starting dose is between 400 mg to 1,200 mg each day.

Elderly and adults weighing under 50 kg
- The usual starting dose is between 200 mg to 400 mg each day.
- Your doctor may decide to increase this dose by 200 mg to 400 mg every 3 to 5 days. Increasing the dose is usual, but do not do this unless your doctor tells you to.
- The maximum dose will depend on your blood levels and illness.

Use in children and adolescents
Priadel tablets are not recommended for children and adolescents.

Patients with kidney problems
Your doctor will monitor the level of lithium in your blood and adjust your dose accordingly. You should not take Priadel tablets if you have severe kidney problems (see Section 2).

Blood Tests
- Within the first week of treatment your doctor will give you a blood test. This is to check the level of lithium in your blood.
- Your daily dose will be changed depending on the results of your blood test.
- Your doctor will carry out a blood test every week until the level of lithium in your blood is steady.
- You will then have your blood tested every 3 months to check that the level remains steady.

If you are going to have other types of blood test, tell the doctor or nurse that you are taking lithium.

If you take more Priadel tablets than you should
If you or someone else has taken more Priadel tablets than you should, talk to a doctor or go to your nearest hospital casualty department straight away. Remember to take the medicine pack with you. This is so the doctor knows what you have taken.

The following effects may happen: feeling sick or being sick, blurred vision, increased need to pass water, lack of control over passing water or stools, feeling lightheaded or drowsy, confusion and blackouts. You may also experience shaking or muscle weakness, muscle twitches and jerks or spasms causing unusual movements of the face, tongue, eyes or neck. In severe cases you may lose consciousness, have fits, shortness of breath or chest pain.

If you forget to take Priadel tablets
If you forget to take a dose at the right time, take it as soon as you remember, then go on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Priadel tablets
Keep taking your medicine until your doctor tells you to stop. Do not stop taking Priadel tablets just because you feel better. If you stop, your illness may return.

When your doctor says that you can stop taking Priadel tablets, 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, this medicine can cause side effects, although not everybody gets them. Side effects are more likely to happen at the start of treatment.

Allergic reactions
If you have an allergic reaction, stop taking Priadel tablets and see a doctor or go to a hospital straight away.
The signs may include: rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Stop taking Priadel tablets and see your doctor or go to a hospital straight away if you notice a combination of any of the following serious side effects.

The following side effects may be signs of lithium toxicity (too much lithium in your blood):
- Loss of appetite, diarrhoea and vomiting (being sick).
- Muscle weakness, lack of co-ordination, muscle twitching or sudden jerks and shaking.
- Feeling drowsy or very tired, balance problems and feeling dizzy with a spinning sensation (vertigo).
- Difficulty in walking or unusual involuntary movements, such as unusual eye movements.
- Ringing in the ears (tinnitus) or blurred vision.
- Difficulty in speaking or slurred speech.
- Altered mental state due to brain disease, damage or malfunction (encephalopathy).

Other serious side effects which need urgent medical attention:
- Swelling around the feet and ankles, face and stomach and weight gain due to water retention.
- Cloudy or foamy urine (water).
- Feeling confused, dazed, delirious or loss of consciousness.
- Memory problems.
- Fits (seizures).
- Irregular or slow heart beats, shortness of breath, chest pain and fainting.
- Involuntary eye movements.
- Abnormal muscle breakdown (rhabdomyolysis) which can lead to kidney problems.
- If you have a high fever, agitation, confusion, trembling, and abrupt contractions of muscles, as these may be signs of a rare condition called serotonin syndrome.
- If you 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.

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).

Tell a doctor or pharmacist straight away if you notice any of the following serious side effects:
- Increased thirst and passing water (urine) more often than normal. You may also feel tired and hungry. This could be due to high blood sugar levels or a condition called 'diabetes insipidus'. It is important to tell your doctor if you are passing more water than usual as the amount of Priadel tablets you are taking may need to be changed.
- You have a swelling or a lump on your neck (which may be caused by an enlarged thyroid gland).
- You have a fast heartbeat, sweating, stress (anxiety), increased appetite, loss of weight, weakness and are unable to tolerate heat. This could be due to higher levels of thyroid hormone in the blood (hyperthyroidism).
- You feel tired, have cold skin and hair becomes dry, thinning of hair or fingernails, hoarse voice, joint or muscle pain and gain weight. This could be due to lower levels of thyroid hormone in the blood (hypothyroidism).
- You have increased thirst, pass more water than usual, feel tired or depressed, muscle aches or pains, bone or joint pain and stomach upsets. This could be due to a hormone problem called 'hyperparathyroidism'
- You have indigestion or heartburn and are feeling sick, being sick or have abdominal pain. You may also have black tarry stools (faeces) or blood in your stools or you may notice blood or dark bits (like coffee grounds) when you are being sick. This could be due to a stomach problem called 'gastritis'.
- Headaches, a 'rushing' sound in your ears and feeling or being sick. This could be because of increased pressure in the brain.

- Numbness, weakness and pain in the arms and legs (peripheral neuropathy).

Tell your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days:
- Hair loss or inflamed hair follicles.
- Acne, skin spots or rashes, skin ulcers and/or itching.
- Slight shaking of the hands.
- You have skin irritation and swelling. Skin may appear red, itchy with silvery scales (psoriasis). If you already have this condition, you could notice that it is getting worse.
- Feeling sick, a watery or dry mouth and/or changes in the way things taste.
- Stomach pain.
- Sexual problems including being unable to get an erection, having delayed ejaculation or being unable to have an orgasm.
- Blurred vision or blind spots in your eyesight.
- Uncontrolled movements of the eye.
- Weight gain.

Frequency, very frequent:
- too much calcium in your blood.

Frequency not known:
- Unmasking and/or aggravation of Brugada Syndrome (a hereditary syndrome that affects the heart)
- Hyperparathyroidism (when the parathyroid glands produce too much parathyroid hormone, which raises calcium levels in the blood).
- Increased size of the parathyroid glands.
- Parathyroid adenoma (a non-cancerous tumour).
- Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome). Stop using Priadel if you develop these symptoms and contact your doctor or seek medical attention immediately.

Tests
Blood tests may show an increase in white blood cells (leucocytosis) or changes in the way the kidney is working. They may also show changes in the levels of calcium or magnesium in your blood.

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

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 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 Priadel tablets
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

- Store below 25°C. Store in the original package to protect from moisture.
- 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. Contents of the pack and other information

What Priadel 200 mg prolonged-release tablets contain
- The active substance is lithium carbonate. Each tablet contains 200 mg lithium carbonate.
- The other ingredients are: Glycerol monostearate, glycerol distearate, mannitol (E421), acacia spray dried, sodium laurilsulfate, magnesium stearate, maize starch and sodium starch glycolate (Type A) (see end of Section 2 for further information about sodium).

What Priadel 400 mg prolonged-release tablets contain
- The active substance is lithium carbonate. Each tablet contains 400 mg lithium carbonate.
- The other ingredients are: Glycerol distearate, mannitol (E421), acacia spray dried, sodium laurilsulfate, magnesium stearate, maize starch and sodium starch glycolate (Type A) (see end of Section 2 for further information about sodium).

What Priadel tablets look like and contents of the pack
Priadel 200 mg prolonged-release tablets are white, scored, capsule-shaped prolonged-release tablets engraved with P200 on one side. They are supplied in blister packs of 100 tablets or securitainers of 100 or 500 tablets. Not all pack sizes may be marketed.

Priadel 400 mg prolonged-release tablets are white, circular, bi-convex tablets engraved PRIADEL on one side, scored on the other side. They are supplied in blister packs of 100 tablets or securitainers of 50, 100 or 1000 tablets or hospital packs of 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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