PACKAGE LEAFLET:
INFORMATION FOR THE USER
Priadel 200mg and 400mg prolonged release tablets
lithium carbonate

SANOFI

Is this leaflet hard to see or read?
Phone 0845 372 7101 for help

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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2. What you need to know before you take Priadel Tablets
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1. What Priadel Tablets are and what they are used for

The name of your medicine is Priadel 200mg or Priadel 400mg 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 (hypersensitive) to lithium carbonate or any of the other ingredients of Priadel Tablets (see Section 6: Further information).

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

Signs of an allergic reaction include: a rash, swelling or breathing problems, swelling of your lips, face, throat or tongue.

- You are breast-feeding.
- You have heart disease.
- You have severe kidney problems.
- You have an under-active thyroid gland that is not being treated.
- You have low levels of sodium in your body. This can happen if you are dehydrated or on a low sodium diet.
- 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.
- 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.

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, 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.

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

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 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 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, chlorothalidone, 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.
• Calcitolin - used for hypercalcaemia and Paget's disease/acute bone loss.

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 fluoxetine, amitriptyline or fluoxetine.
• Medicines used to calm emotional and mental illnesses - such as haloperidol, flupenthixol, diazepam, thoridazine, amisulpride, fluphenazine, chlorpromazine or clozapine.
• Coadministration with Priadel 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 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
Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

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 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).

Important information about some of the ingredients of Priadel Tablets
Your medicine contains mannitol (E421). This may cause mild diarrhoea.

3. How to take Priadel Tablets

Always take Priadel Tablets exactly as your doctor has told you. You should 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 tablets whole. Do not crush or chew them.
• The tablets can be broken in half.
• Take your medicine at the same times every day.
• Do not take Priadel Tablets if you are pregnant, especially in the first 3 months of your pregnancy.
• The usual starting dose is between 200mg to 1,200mg each day.
• The usual starting dose is between 200mg to 400mg each day.
• Your doctor may decide to increase this dose by 200mg to 400mg every 3 to 5 days. Increasing the dose is usual, but do not do this unless your doctor tells you to.
Stop taking Priadel and see your doctor or go to a hospital straight away if you notice 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, diarrhea 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 stores), or passing less water than usual.
- 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.

Frequency unknown:

- Benign/malignant kidney tumours (microcysts, oncocytoma, or collecting duct renal carcinoma) (in long-term therapy).

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 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 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 higher levels of thyroid hormone in the blood (hyperthyroidism).
- 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’.

4. Possible side effects

Like all medicines, Priadel Tablets 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 and see a doctor or go to a hospital straight away.

The signs may include: rash, swelling or breathing problems, swelling of your lips, face, throat or tongue.
• 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.

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 out of the reach and sight of children.
• Do not use Priadel Tablets 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 25ºC. Store in the original package to protect from moisture.
• Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information
What Priadel 200mg prolonged release tablets contain
• Each tablet contains 200mg of the active substance, lithium carbonate.
• The other ingredients are: Glycerol monostearate, glycerol distearate, mannitol (E421), acacia spray dried, sodium laurolsulfate, magnesium stearate, maize starch and sodium starch glycolate (Type A).

What Priadel 400mg prolonged release tablets contain
• Each tablet contains 400mg of the active substance, lithium carbonate.
• The other ingredients are: Glycerol distearate, mannitol (E421), acacia spray dried, sodium laurolsulfate, magnesium stearate, maize starch and sodium starch glycolate (Type A).

What Priadel Tablets look like and contents of the pack
Priadel 200mg prolonged release tablets are white, scored, capsule-shaped 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 400mg 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.

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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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Bipolar UK is a charity which can provide more information about manic depression/bipolar disorder. They can be contacted by:
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