

Consumer Medicine Information

PRIADEL®

400 mg prolonged release tablets

Lithium carbonate

What is in this leaflet

This leaflet answers some common questions about PRIADEL. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking PRIADEL against the benefits he/she expects it will have for you. If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What PRIADEL is used for

PRIADEL is used for the treatment of mania and hypomania, recurrent bipolar depression, and prophylactic treatment of recurrent affective disorders. Lithium carbonate provides a source of lithium, which competes with sodium at various sites in the body.

Before you take PRIADEL

Do not take PRIADEL if:

- you have an allergy to PRIADEL or any of the ingredients listed at the end of this leaflet
- you have problems passing urine or have an impairment of kidney function, or if you have significant renal disease.
- you have an impairment of heart function
- you are on a low sodium diet or have a condition associated with low sodium levels, such as Addison's disease
- you are breastfeeding
- you have untreated hypothyroidism (an under-active thyroid gland that is not being treated)
- 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, heart arrest or sudden death.
- you are having, or going to have electroconvulsive therapy (ECT)
- you are going to have any major operation or surgery
- you are under the 12 years of age (PRIADEL is not recommended in adolescents and children)

Tell your doctor if:

- you have any other medical conditions (e.g. issues with parathyroid function, a family history of endocrine disease, congenital long QT syndrome).
- you are taking lithium in any other form
- you are pregnant, or intend to become pregnant or to breastfeed. Lithium may be harmful to the fetus and newborn baby, so PRIADEL should not be used during pregnancy unless considered essential. Lithium is secreted into breast milk, so PRIADEL should not be used during breastfeeding. Effective contraception throughout PRIADEL treatment should be considered and a joint decision with your doctor should be made when considering of PRIADEL treatment in pregnancy.

- 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 are taking Topiramate (used to treat epilepsy or migraine)
- you are taking any other medicines such as medicines which affect renal clearance of lithium and electrolyte balance (e.g. NSAIDs, diuretics), may cause neurotoxicity (e.g. neuroleptics), or affect heart rhythm (e.g. quinidine, disopyramide, amiodarone)
- 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.

Your doctor might arrange for blood tests and other health checks to be carried out prior to and during treatment with PRIADEL.

Treatment with PRIADEL tablets requires regular monitoring of serum lithium levels. Your doctor will arrange for the necessary blood tests to be carried out. Frequent blood tests are required at the start of treatment. The period between blood tests is then increased gradually up to about three months. Additional blood tests may be required following alteration of your dosage, a change in your condition or other illness, or following a significant change in your sodium (e.g. salt) or fluid intake.

Taking other medicines

It is very important that you tell your doctor if you are taking any other medicines, including any non-prescription products. The combination of PRIADEL with other medicines may lead to increased side effects, and your doctor may have to adjust your dose of PRIADEL if you are taking certain other medicines.

How to take PRIADEL

Take PRIADEL only when prescribed by your doctor. Your doctor will tell you how many tablets you need to take each day. The dose will vary depending on the condition being treated. Your age and weight may also be reviewed as part of the initial dose selection. Older patients often require lower doses.

Carefully follow all the directions given to you by your doctor. They may differ from the information contained in this leaflet. If you do not understand how to take the medicine, ask your doctor or pharmacist for help.

PRIADEL tablets are normally taken as a single daily dose, in the morning or on retiring. Alternatively, the dose may be divided and given morning and evening. PRIADEL should be taken at the same time each day.

PRIADEL tablets should be taken with food, as this causes less nausea than on an empty stomach. The tablets should not be crushed, chewed or swallowed with hot liquids. PRIADEL tablets are scored, so they can be divided accurately to provide dosages to the nearest 200 mg.

Do not stop taking PRIADEL without consulting your doctor.

During treatment with PRIADEL, you should try to ensure a constant diet and fluid intake and avoid circumstances which may cause excessive sodium loss such as heavy exercise leading to excessive sweating. This will help maintain a stable salt and water balance. This applies particularly in hot weather and during periods of illness.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your doses as you would normally. If you are not sure whether to skip the dose, talk to your doctor or pharmacist. Do not take a double dose to make up for the dose that you missed.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PRIADEL. All medicines can have side effects. Sometimes they are serious but most of the time they are not. You may need medical treatment if you experience some of the side effects, particularly lithium intoxication (see below).

The side effects of PRIADEL are usually related to high serum lithium concentrations. The more common side effects are listed below. Elderly patients may be more sensitive to these side effects.

- Mild gastrointestinal disturbances, nausea, vertigo, muscle weakness and a dazed feeling may occur on commencing treatment with PRIADEL, but frequently disappear after stabilisation of dose.
- Fine hand tremors.
- An increase in urine output and mild thirst.
- Weight gain or fluid retention.
- Skin conditions including acne, psoriasis, rashes and leg ulcers may be aggravated by lithium treatment.
- Long term treatment may be associated with disturbances of calcium levels (e.g. too much calcium in your blood), thyroid function, parathyroid function and memory impairment.
- Up to one third of patients may develop some impairment of kidney function.
- Anorexia
- constipation or diarrhoea
- epigastric discomfort
- metallic taste
- headache

Other possible side effects are listed below.

- 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.

Inform your doctor if you experience any of the following:

- infectious diseases, including colds, influenza, gastro-enteritis and urinary infections
- excessive urine output or thirst
- episodes of nausea and vomiting, or other conditions that may lead to salt or water depletion (including severe dieting)
- swelling of the face, lips, mouth, tongue or throat.
- weakness, lethargy, fever, tremulousness, confusion, movement symptoms and elevated white blood cell count
- persistent headache and/or visual disturbances
- symptoms of serotonin syndrome:
 - Mental status changes (agitation, confusion, hypomania, coma)
 - Neuromuscular abnormalities (involuntary muscle spasms, tremor, overresponsive reflexes, rigidity, akathisia)
 - Autonomic hyperactivity (muscle movement symptoms, rapid heartbeat, shivering, high body temperature, excessive sweating)
 - Gastrointestinal symptoms (diarrhoea)

If you experience any of the following symptoms of lithium intoxication, you should stop taking your PRIADEL tablets and immediately contact your doctor:

1. Gastro-intestinal symptoms, e.g.:
 - anorexia or loss of appetite
 - diarrhoea
 - vomiting
 - dehydration

2. Central nervous system symptoms, e.g.:
 - muscle weakness
 - lack of co-ordination
 - drowsiness or lethargy
 - giddiness
 - movement disorders
 - tinnitus
 - blurred vision
 - confusion
 - nystagmus (rapid, involuntary eye movements that cause the eye to flicker)
 - slurred speech
 - coarse tremor and muscle twitching
 - disorientation
 - seizures

3. Central nervous system symptoms, e.g.:
 - changes in rhythm or rate of heart beat

If you become pregnant while taking PRIADEL, tell your doctor immediately.

Overdose

Immediately telephone your doctor or the National Poisons Information Centre (telephone **0800 POISON** or **0800 764 766**) for advice if you think that you or anyone else may have taken too much PRIADEL. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers of these places handy.

Lithium intoxication may occur if your serum lithium level is too high. If you experience any of the symptoms of lithium intoxication listed above under Side Effects, you should stop taking your PRIADEL tablets and immediately contact your doctor.

Storage conditions

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

Keep all medicines out of the reach of children.

Do not use PRIADEL if the product has passed the expiry date on the pack.

Product description

PRIADEL is a white, scored tablet, containing 400 mg lithium carbonate in a controlled release form.

Packets of PRIADEL contain 100 tablets.

Inactive ingredients

- Mannitol
- Acacia
- Sodium laurilsulfate
- Glyceryl palmito-stearate
- Maize starch
- Magnesium stearate
- Sodium starch glycolate

PRIADEL tablets do not contain any sugar, gluten or colouring agent.

Supplier

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