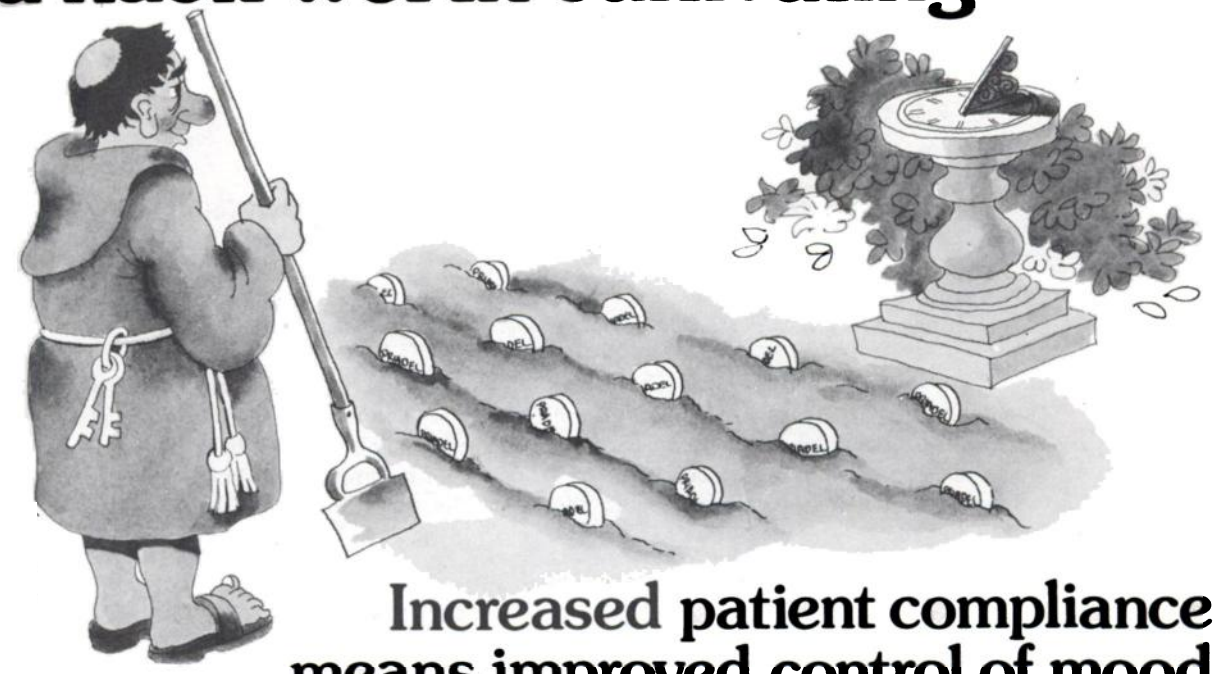
Once daily Priadel is a habit worth cultivating.



Increased patient compliance means improved control of mood

priadel TRADEMARK

Lithium carbonate B.P., controlled release

Further information is available to the medical profession on request from:
Delandale Laboratories Limited, Delandale House, 37 Old Dover Road, Canterbury, Kent. Tel. Canterbury 66353.

PRIADEL®

Presentation Controlled release lithium carbonate tablets: white, circular, scored bi-convex tablets engraved PRIADEL one side. Each tablet contains 400 mg Lithium Carbonate BP in a controlled release dosage form.

Uses Controlled release lithium therapy for:
a) The treatment of manic, hypomanic and depressive episodes of recurrent affective disorders.
b) Prophylaxis against relapse in recurrent mania, manic depressive illness and depressions.

Dosage and administration A simple treatment schedule has been evolved, which, except for some minor variations, should be followed whether using PRIADEL therapeutically or prophylactically. The minor variations to this schedule depend on the elements of the illness being treated and these are described later.

1. In patients of average weight (70 kg), 3–4 tablets (1,200–1,600 mg) of PRIADEL are given as a single daily dose in the morning or on retiring. In elderly patients or those below 50 kg, it is recommended that the starting dose be reduced to 2 tablets (800 mg). The tablets should not be crushed, chewed or swallowed with hot liquids. When changing from other lithium preparations, serum lithium levels should be first checked, then PRIADEL therapy commenced at a daily dosage as close as possible to the dosage of the other form of lithium.

2. Four to five days after starting treatment (and never longer than one week), a blood sample should be taken before the daily dose of tablets for the estimation of serum lithium levels.

3. If necessary, the dose of PRIADEL is adjusted by half to 1 tablet to maintain serum lithium levels between 0.6–1.5 m.mol/L (=mEq/L). Serum lithium levels should be monitored on a weekly basis until stabilisation is achieved.

4. Following stabilisation of serum lithium levels, the time interval between subsequent estimations can be gradually increased, but should not normally exceed three months.

5. Careful clinical appraisal of the patients should be exercised throughout medication.

6. Priadel should be continued through any recurrence of the affective disturbance. This is important as the full prophylactic effect may not occur for 6–12 months after the initiation of therapy.

7. Thyroid function tests should be performed approximately once yearly. A small number of patients may show drug induced hypothyroidism which may be treated successfully with concurrent thyroxine.

Treatment of acute mania and hypomania: It is likely that a higher than normal PRIADEL intake may be necessary in the acute phase. Therefore, as soon as control of the mania is achieved, the serum lithium level should be determined and it may be necessary, dependent on the results, to lower the dosage of PRIADEL and re-stabilise serum lithium levels. In all other details, the described treatment schedule is recommended.

Prophylaxis against recurrent mania and hypomania, manic depressive illness, recurrent depression and treatment of depression: It is recommended that the described treatment schedule is followed.

Contra-indications, warnings, etc When contemplating Priadel therapy ascertain whether patients are receiving lithium in any other form; if so check serum levels before proceeding. It is important to ensure that renal function is normal; if necessary a creatinine clearance test or other renal function tests should be performed. Renal insufficiency, cardiac insufficiency, Addison's disease and frank hypothyroidism are all contra-indications to lithium therapy. Treatment should be discontinued during any intercurrent renal infection, and should only be reinstituted when kidney function has returned to normal.

Caution should be exercised to ensure that diet and fluid intake are normal, thus maintaining a normal electrolyte balance. This may be of special importance in very hot weather. Infectious diseases including colds, influenza, gastro-enteritis and urinary infections may alter fluid balance and thus affect serum lithium levels.

Although there are reports of the safe use of PRIADEL during pregnancy it is recommended as a general rule that PRIADEL be discontinued during a planned or confirmed pregnancy. If it is considered essential to maintain Priadel treatment during pregnancy serum lithium levels should be closely monitored since renal function alters gradually during pregnancy and suddenly at parturition, thus requiring dosage adjustments. Babies may show signs of lithium toxicity necessitating fluid therapy in the neonatal period. Lithium is secreted in breast milk and bottle feeding is recommended.

Side-effects: Transient side-effects may occur during the stabilisation but are unlikely to do so at serum lithium levels below 2.0 m.mol/L. They are most commonly a fine tremor of the hands, mild polydipsia, mild polyuria, initial anorexia, some loosening of the stools and, more rarely, nausea or diarrhoea. In these cases it is advisable to check serum lithium levels. Weight gain or oedema may present in some patients.

Toxic effects: Such effects are indicative of impending lithium intoxication and they fall into two groups:
a) Gastro-intestinal: increasing anorexia, diarrhoea and vomiting.
b) Central nervous system: mild drowsiness and sluggishness increasing to giddiness with ataxia, a coarse tremor of the extremities and lower jaw, tinnitus, blurred vision, muscular twitching, dysarthria progressing (above 2–3 m.mol/L) to seizures, coma and death.

If any of the above symptoms appear, the patients should be instructed to stop taking their tablets and report for an immediate serum lithium estimation.

Lithium intoxication: There is no specific antidote to lithium poisoning. In the event of accumulation, lithium should be stopped and serum estimations should be performed every six hours to ensure that the lithium level is falling at a rate corresponding to a half life of under 30 hours.

Under no circumstances should a diuretic be used. Promote osmotic diuresis (Mannitol or urea infusion) or alkalinisation of the urine (sodium lactate or sodium bicarbonate infusion). If there is a deterioration in the patient's condition, or if the serum level is over 4.0 m.mol/L, peritoneal or haemodialysis should be promptly instituted. This should be continued until there is no lithium in the serum or dialysis fluid. Serum lithium levels must be monitored for at least a further week to take account of any possible rebound in serum lithium levels as a result of diffusion from body tissues.

Drug interactions: An anti-diuretic effect leading to water retention has been reported following the use of diuretics during treatment with lithium salts. There is a possibility of water intoxication and lithium intoxication when diuretics and lithium salts are co-prescribed. Any drugs affecting electrolyte balance (e.g. diuretics, appetite suppressants, steroids) may alter lithium excretion and should be avoided in patients on lithium. If other psychotropic drugs are used they should be initiated at a lower dosage than usual as their side-effects may be potentiated by the use of lithium. This has been shown to be of particular importance for the concurrent use of lithium and haloperidol.

Pharmaceutical precautions Cool conditions of storage required. Tablets should not be crushed nor any attempt made to dissolve them before administration.

Legal category POM

Package quantities Tubes of 100 and 1,000 tablets. Fibre drums of 10,000 tablets.

Further information Nil

Product licence number 0357/5000

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