Only for the use of Medical Professionals

Litiam® ER

Lithium Carbonate

Description

Litiam® ER is a preparation of Lithium carbonate which provides a source of lithium ions that may act by competing with sodium ions at various sites in the body. Therapeutic concentrations of lithium have almost no discernible psychotropic effects in normal volunteers but considerable effect in patients suffering from affective disorders. The mechanism of action is unknown.

Indications

Litiam® ER is indicated for the-

- Treatment and prophylaxis of mania, manic depressive illness and recurrent depression
- Treatment of aggressive or self mutilating behaviour

Dosage and administration

Adults:

Litiam® ER tablets are usually administered according to a twice daily regimen. When Lithium levels have stabilized, a once daily regimen may be preferred.

For Acute Mania: Initial treatment dose is 1-1.5g daily for the first five days.

Prophylaxis of recurrent affective disorders (Including unipolar mania & unipolar depressions and bipolar manic-depressive illness) : A low dose of 300-400 mg of lithium carbonate can be administered daily for the first seven days. Dose of Litiam is adjusted to keep the plasma lithium level within the range of 0.4-0.8 mmol/l.

For Aggressive and self-mutilating behavior: Dosage is at the lower end of the range for the treatment of manic depressive illness.

Elderly:

Elderly patients often require lower lithium dosage to achieve therapeutic serum levels. As for prophylaxis, Lithium levels should be kept in the range of 0.4-0.7 mmol/l.

Children: Not recommended.

Use in pregnancy and lactation

Avoid if possible in the first trimester due to have the risk of teratogenicity, including cardiac abnormalities; dose may be increased during the second and third trimesters but on delivery return abruptly to normal dose. Close monitoring of serum-lithium concentration is advised to avoid the risk of toxicity in neonate.

Nursing Mothers: Lithium is secreted in breast milk, therefore bottle feeding is recommended.

Side Effects

The most frequent adverse effects are the initial post-absorptive symptoms, believed to be associated with a rapid rise in serum lithium levels. They include gastrointestinal discomfort with mild nausea and diarrhea, vertigo, muscle weakness and a dazed feeling and frequently disappear after stabilization of therapy. The more common and persistent adverse reactions are fine tremor of the hands, fatigue, thirst and polyuria. At higher concentrations, ataxia, tinnitus, blurred vision, giddiness and increasing polyuria are seen. Long term administration of lithium carbonate may precipitate goiter requiring treatment with thyroxine, but this regresses when treatment is discontinued.

Precautions

Pretreatment physical examination and laboratory testing are required prior to commencement of therapy and should be repeated at frequent intervals. The patient should maintain a normal diet with adequate salt and fluid intake during therapy. Lithium toxicity is closely related to serum lithium concentrations and can occur at doses close to therapeutic concentrations. Diuretics should not be used during lithium therapy without appropriate dosage adjustment. Serum lithium concentration should be measured regularly (every 3 months on stabilized regimens). Renal function and thyroid function should also be measured every 6 months intervals.

Contraindications

It is contraindicated in patients with known hypersensitivity to active ingredient or any component of the product, in patients with significant cardiovascular disease or renal impairment, untreated hypothyroidism, conditions associated with hyponatremia (Addison's disease, dehydrated or severely debilitated patients, patients on low sodium diets).

Drug interaction

Lithium dosage should either be adjusted or stopped during concomitant treatment as these increase or decrease the concentration of Lithium. Lithium concentration may be increased when SSRIs, Metronidazole, Tetracyclines, Topiramate, Non-steroidal anti-inflammatory drugs (NSAID), ACE inhibitors, Thiazide diuretics (may cause a paradoxical antidiuretic effect resulting in possible water retention and lithium intoxication), Spironolactone, Frusemide, Angiotensin-II receptor antagonists, steroids are taken concomitantly. Lithium concentration may be decreased when Xanthines (theophylline, caffeine), Sodium bicarbonate and Sodium Chloride containing products, Psyllium or Ispaghula husk, Urea, Mannitol, Acetazolamide are taken. It may cause neurotoxicity when taken with Neuroleptics (risperidone, clozapine, phenothiazines, and particularly haloperidol), SSRIs, Sumitriptan and Tricyclic Antidepressants, Calcium channel blockers, Carbamazepine or phenytoin, Methyldopa.

Overdose

Over dosage usually with serum lithium concentration of over 1.5 mmol/litre may be fatal and toxic effects include tremor, ataxia, dysarthria, nystagmus, renal impairment and convulsions. If these potentially hazardous signs occur, treatment should be stopped, serum lithium concentrations redetermined and steps taken to reverse lithium toxicity. In mild cases withdrawal of Lithium and administration of sodium salts and fluid will reverse the toxicity. A serum lithium concentration in excess of 2 mmol/litre requires urgent treatment. (BNF). Haemodialysis is the treatment of choice for severe poisoning and should be considered in all patients with marked neurological features.There is no known antidote to lithium poisoning and activated charcoal does not adsorb lithium. Sodium-depleting diuretics should not be used in any circumstances. All patients should be observed for a minimum of 24 hours. ECG should be monitored in symptomatic patients. Steps should be taken to correct hypotension.

Pharmaceutical precautions

Store in a cool, dry place. Protect from light. Keep out reach of children

Presentation

Litiam® ER tablet: Each extended release tablet contains Lithium carbonate USP 400 mg.

Package quantities

Litiam® ER tablet: Carton of 40 tablets per pack.

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Narayanganj, Bangladesh