LICAB XL

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for LICAB XL
(Lithium Carbonate Prolonged-Release Tablets I.P)
[Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action: The precise mechanism of action of lithium as a mood-stabilising agent remains unknown, although many cellular actions of lithium have been characterised.

INDICATION: In the treatment of Anti-Depression.

DOSAGE AND ADMINISTRATION: Uncoated tablet, 400 mg tablets are usually administered according to a twice daily regimen.

CONTRAINDICATION: • Hypersensitivity to the active substance or to any of the excipients listed, Severely impaired renal function, Untreated or untreatable hypothyroidism, Cardiac disease associated with rhythm disorder, Brugada syndrome or family history of Brugada syndrome, Low body sodium levels for example dehydrated patients, those on low sodium diets, or those with Addison's disease, Breast-feeding.

WARNINGS & PRECAUTIONS: Lithium carbonate has a narrow therapeutic window. The dose required for treatment must be titrated and adjusted on the basis of regular monitoring of serum concentration of lithium. Lithium therapy should not be initiated unless adequate facilities for routine monitoring of plasma concentrations are available. Elderly patients are particularly liable to lithium toxicity. Use with care as lithium excretion may also be reduced. They may also exhibit adverse reactions at serum levels ordinarily tolerated by younger patients. ***Before beginning a lithium treatment:*** It is important to ensure that renal function is evaluated, Thyroid function should be evaluated. Patients should be euthyroid before initiation of lithium therapy, Cardiac function should be assessed especially in patients with cardiovascular disease, Renal, and cardiac and thyroid functions should be re-assessed periodically. ***Risk of convulsions:*** may be increased when lithium is co-administered with drugs that lower the epileptic threshold, or in epileptic patients. ***Benign intracranial hypertension:*** There have been case reports of benign intracranial hypertension. Patients should be warned to report persistent headache and/or visual disturbances. ***QT prolongation:*** As a precautionary measure, lithium should be avoided in patients with congenital long QT syndrome, and in patients concomitantly treated with drugs that are known to prolong the QT interval. Caution should be exercised in patients with risk factors for QT interval prolongation (which include cardiac disease, bradycardia, thyroid disease, hypokalaemia, hypomagnesaemia, hypocalcaemia, female sex and advanced age. ***Brugada syndrome:*** Lithium may unmask or aggravate Brugada syndrome, a hereditary disease of the cardiac sodium channel with characteristic ECG changes (right bundle branch block and ST segment elevation in right precordial leads), which may lead to cardiac arrest or sudden death. Lithium should not be administered to patients with Brugada syndrome or a family history of Brugada syndrome Caution is advised in patients with a family history of cardiac arrest or sudden death. ***Concomitant administration of antipsychotics:*** Concomitant administration of antipsychotics should be avoided.

DRUG INTERACTIONS: Interactions may occur as a result of increased or decreased lithium levels, or may act through other mechanisms, the most important being neurotoxicity which may occur at therapeutic levels when other drugs which act centrally on the CNS are taken concurrently. ***Interactions which increase lithium concentrations:*** Any drug which may cause renal impairment has the potential to cause lithium levels to rise, thereby causing toxicity. If the use of the drug is unavoidable, carefully monitor lithium blood level and adapt dosage as necessary. ***Interactions which decrease serum lithium concentrations:*** Xanthine derivatives, sodium bicarbonate, Carbonic anhydrase inhibitors, Urea. ***Interactions which may not be associated with increased or reduced lithium levels:*** Antipsychotics,

Carbamazepine, Phenytoin and Methyldopa. ***Drugs which lower seizure threshold:*** antidepressants, antipsychotics. ***Drugs which prolong the QT interval:*** Class Ia antiarrhythmics, Class III antiarrhythmics, Antibiotics, Serotonin antagonists, Antihistamines and Antimalarials.

ADVERSE REACTIONS: Side effects are usually related to serum lithium concentrations and are less common in patients with plasma lithium concentrations below 1.0 mmol/l. Initial Therapy: fine tremor of the hands, polyuria and thirst may occur. ***Blood and lymphatic system disorders:*** leucocytosis. ***Immune system disorders:*** increase in antinuclear antibodies. ***Endocrine disorders:*** disturbances of thyroid function including (euthyroid) goitre, hypothyroidism and hyperthyroidism, hyperparathyroidism, parathyroid adenoma. ***Metabolism and nutrition disorders:*** hypercalcaemia, hypermagnesaemia, hyperglycaemia, anorexia, weight gain. ***Psychiatric disorders:*** Delirium ***Nervous system disorders:*** coma, benign intracranial hypertension, syndrome of irreversible lithium effectuated neurotoxicity (SILENT), encephalopathy, stupor, seizures, neuroleptic malignant syndrome, myasthenia gravis, serotonin syndrome, parkinsonism, extrapyramidal symptoms, ataxia, dizziness, memory impairment, mild cognitive impairment may occur during long term use, giddiness, nystagmus, slurred speech, vertigo, hyperactive deep tendon reflexes, dazed feeling, fine hand tremors. ***Eye Disorders:*** scotomata and blurred vision. ***Cardiac disorders:*** cardiac arrest, ventricular fibrillation, ventricular tachycardia, ventricular arrhythmias, Torsade de pointes, QT interval prolongation, cardiomyopathy, arrhythmia, bradycardia, sinus node dysfunction, ECG changes. ***Vascular disorders:*** peripheral circulatory collapse, hypotension. ***Gastrointestinal disorders:*** gastritis, nausea, diarrhoea, vomiting, dry mouth, excessive salivation. Lithium salts have been implicated in dysgeusia. ***Skin and subcutaneous tissue disorders:*** Allergic rash, exacerbation of psoriasis, acneiform eruptions, alopecia, acne, papular skin disorder, folliculitis, pruritus, rash. Frequency not known: lichenoid drug reaction ***Musculoskeletal and connective tissue disorders:*** muscle weakness, rhabdomyolysis. ***Renal and urinary disorders:*** symptoms of nephrogenic diabetes insipidus, impairment of renal function, permanent changes in the kidney, nephrotic syndrome, histological renal changes with interstitial fibrosis after long term treatment, polyuria, polydipsia. Frequency unknown: Micro cysts, oncocytoma and collecting duct renal carcinoma (in long-term therapy) ***Reproductive system and breast disorders:*** sexual dysfunction. ***General disorders and administration site conditions:*** sudden unexplained death, oedema, asthenia, lethargy, thirst, fatigue**,** and malaise can occur due to lithium toxicity. Some adverse events will be seen when Lithium levels are raised – for symptoms see section

MARKETED BY:

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(Additional information is available on request)