HOW SUPPLIED: Lithium Carbonate Extended-release Tablets, USP are available containing 300 mg of lithium carbonate, USP.

The 300 mg extended-release tablets are peach film-coated, round, uncoated tablets embossed with ‘M’ on one side of the tablet and ‘LC’ over 300 on the other side. They are available as follows.

NDC 54479-180-20 - Unit dose blister packages of 100 (10-cents of 10 tablets each).

Store at 20°C to 25°C (68°F to 77°F). (See USP Controlled Room Temperature.)

Protect from moisture.

DESCRIPTION: Lithium carbonate extended-release tablets, USP contain lithium carbonate, USP, a white, granular, odorless powder with molecular formula Li2CO3, and molecular weight 73.89. It is sparingly soluble in water, very slightly soluble in absolute alcohol, and with effervescence in dilute mineral acids. Lithium is an element of the alkaline earth group with atomic number 3, atomic weight 6.94 and an emission line at 671 nm on the flame photometer. Each peach film-coated, extended-release tablet contains 300 mg of lithium carbonate, USP. This slow-dissolving film-coated tablet is designed to give lower serum lithium peak concentrations than obtained with conventional oral lithium dosage forms. Inactive ingredients consist of calcium stearate, hypromellose, polydextrose, povidone, polyethylene glycol, red iron oxide, sodium chloride, lactose monohydrate, sorbitol, titanium dioxide, triacetin and yellow iron oxide.

Lithium Carbonate Extended-release Tablets USP 300 mg needs USP Dissolution Test 4.

CLINICAL PHARMACOLOGY: Preclinical studies have shown that lithium alters sodium transport in nerve and muscle cells and effects a shift toward intracellular metabolism of catecholamines, but the specific biochemical mechanism of lithium action in man is unknown.

INDICATIONS AND USAGE: Lithium carbonate extended-release tablets are indicated in the treatment of manic episodes of Bipolar Disorder. Bipolar Disorder: Manic (DSM-IV) is equivalent to Manic Depressive Ailments, Mania in the older DSM-II terminology. Lithium carbonate extended-release tablets are also indicated as a maintenance treatment for individuals with a diagnosis of Bipolar Disorder. Maintenance therapy reduces the frequency of manic episodes and decreases the intensity of those episodes, which may occur in untreated patients. Typical symptoms of mania include pressure of speech, motor hyperactivity, restlessness, need for sleep, flight of ideas, grandiosity, altered judgment, aggressiveness and possibility hostility. When given to a patient experiencing a manic episode, lithium may produce a normalization of symptomatology within 1 to 3 weeks.

WARNING: Lithium Toxicity: Lithium toxicity is closely related to serum lithium concentrations and can occur at levels close to therapeutic concentrations (see DOSAGE AND ADMINISTRATION).

Caution: and their families should be informed that the patient must discontinue lithium therapy and contact his physician if such clinical signs of lithium toxicity as dizziness, vomiting, tremors, mild lassitude, sleeplessness or muscular weakness occur.

Lithium should generally not be given to patients with significant renal or cardiovascular disease, severe dehydration, dehydrating, sodium depletion, and to patients receiving diuretics; or patients converting any MAOI inhibitors, since the risk of lithium toxicity is very high in such patients. If the psychiatric indication is life threatening and if such a patient fails to respond to other measures, lithium treatment may be undertaken with extreme caution, including daily serum lithium determinations and adjustment to the usually low dose ordinarily tolerated by these individuals. In such instances, hospitalization is a necessity.

Unmasking of Brugada Syndrome: There have been post-marketing reports of a possible association between treatment with lithium and the unmasking of Brugada Syndrome. Brugada Syndrome is a disorder characterized by abnormal electrocardiographic (ECG) findings and a risk of sudden death. Lithium should generally be avoided in patients with Brugada Syndrome or those suspecting of having Brugada Syndrome. Consultation with a cardiologist is recommended if: (1) treatment with lithium is under consideration for patients suspected of having Brugada Syndrome or patients who have risk factors for Brugada Syndrome, e.g., unexplained syncope, a family history of sudden unexplained death before the age of 45 years, (2) patients who develop unexplained syncope or palpitations after starting lithium therapy.

Renal Effects: Chronic lithium therapy may be associated with diminution of renal concentrating ability, renal papillary necrosis, presenting as nephrogenic diabetes insipidus, with polyuria and polydipsia. Such patients should be carefully managed to avoid dehydration and potassium depletion.

This condition is usually reversible when lithium is discontinued.

Morphologic changes with glomerular and intestinal fibrosis and expressing apoptosis have been reported in patients on chronic lithium therapy. Morphologic changes have also been seen in manic-depressive patients never exposed to lithium. The relationship between renal function and morphologic changes and their association with lithium therapy have not been established.

Kidney function should be assessed prior to and during lithium therapy. Routine urinalysis and other tests may be used to evaluate tubular function (e.g., urine specific gravity or osmolality following a period of water deprivation or 24-hour urine volume) and glomerular function (e.g., serum creatinine or creatinine clearance). During lithium therapy, progressive or sudden changes in renal function, even within the normal range, indicate the need for ren evaluation of treatment.

Encephalopathic Syndrome: An encephalopathic syndrome characterized by weakness, lethargy, fever, tremors and confusion, extrapyramidal symptoms, leukopenia, elevated serum enzymes, BUN and FBS has occurred in a few patients treated with lithium plus a neuroleptic, most notably haloperidol. In some instances, the syndrome was followed by irreversible brain damage. Because of possible causal relationship between these events and the concomitant administration of lithium and neuroleptic drugs, patients receiving such combined therapy or patients with renal failure, or concomitant use of lithium and neuroleptic drugs should be monitored closely for early signs of neurologic toxicity and treatment discontinued promptly if such signs appear. This encephalopathic syndrome may be similar to or the same as Neuroleptic Malignant Syndrome (NMS).

Concurrent Use with Neuronal Blocking Agents: Lithium may potentiate the effects of neuromuscular blocking agents. Therefore, neuromuscular blocking agents should be given with caution to patients receiving lithium.

Usage in Pregnancy: Adverse effects on radiation in rats, embryo viability in vitro and metastasis in vivo of rat testis and human spermatozoa have been attributed to lithium, as have teratogenicity in subhuman primates and fetal malformations in rats.

In humans, lithium may cause fetal harm when administered to a pregnant woman. Data from lithium births reportssuggest an increase in cardiac and other anomalies, especially Ectopia lens. If this drug is used in women of childbearing potential, or during pregnancy, or if a patient becomes pregnant while taking this drug, the patient should be apprised by their physician of the potential hazard to the fetus.

Usage in Nursing Mothers: Lithium is excreted in human milk. Nursing should not be undertaken during lithium therapy except in rare and unusual
increase the risk of neurotoxicity in the form of ataxia, tremors, nausea, and vomiting. Concurrent extended-use of iodide preparations, especially potassium alka\-linizing agents such as sodium bicarbonate, may also increase toxicity due to reduced renal clearance. Patients receiving such combined therapy should be monitored closely.

Adverse reactions may be encountered at serum lithium concentrations exceeding 2 mEq/L during the acute treatment phase. In general, the occurrence and severity of adverse reactions are directly related to serum lithium concentrations and to individual patient sensitivity to lithium. They generally occur more frequently and with greater severity at higher concentrations. Adverse reactions at serum lithium concentrations generally subside as lithium therapy is continued at serum lithium concentrations below 1.5 mEq/L. Mild to moderate adverse reactions may occur at concentrations near the therapeutic range and may persist until serum lithium concentrations are normalized. Some patients may exhibit signs of toxicity at serum concentrations below 2.0 mEq/L. If serum lithium concentrations are significantly above the therapeutic range, elimination of this ion from the body may be required.

The following signs and symptoms may occur: fine hand tremor, polyuria and mild thirst may occur during initial therapy and may be associated with intolerance of background rhythm. The occurrence and severity of adverse reactions are generally directly related to serum lithium concentrations and to individual patient sensitivity to lithium. They generally occur more frequently and with greater severity at higher concentrations. Adverse reactions at serum lithium concentrations generally subside as lithium therapy is continued at serum lithium concentrations below 1.5 mEq/L. Mild to moderate adverse reactions may occur at concentrations near the therapeutic range and may persist until serum lithium concentrations are normalized. Some patients may exhibit signs of toxicity at serum concentrations below 2.0 mEq/L. If serum lithium concentrations are significantly above the therapeutic range, elimination of this ion from the body may be required.

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HOW SUPPLIED: Lithium Carbonate Extended-release Tablets, USP are available containing 300 mg of lithium carbonate, USP.

The 300 mg extended-release tablets are peach film-coated, round, uncoated tablets embossed with M on one side of the tablet and E over 300 on the other side. They are available as follows:

NDC 50179-180-20 - Unit dose blister packages of 10 (10-cards of 10 tablets each).

Store at 20°-25°C (68° to 77°F). (See USP Controlled Room Temperature.) Protect from moisture.

DESCRIPTION: Lithium carbonate extended-release tablets, USP, contain lithium carbonate, USP, a white, granular, odorless powder with molecular formula Li2CO3 and molecular weight 73.89. It is sparingly soluble in water, very slightly soluble in alcohol and solutions, with opalescence in dilute mineral acids. Lithium is an element of the alkali metal group with atomic number 3, atomic weight 6.94 and an emission line at 671 nm on the flame photometer. Each peach film-coated, extended-release tablet contains 300 mg of lithium carbonate, USP. This slow-dissolving film-coated tablet is designed to give lower serum lithium peak concentrations than obtained with conventional oral lithium dosage forms. Active ingredients consist of calcium stearate, hypromellose, polydextrose, povidone, polyethylene glycol, red iron oxide, sodium chloride, talc, lauryl sulfoc, sorbitol, titanium dioxide, triacetin and yellow iron oxide.

Lithium Carbonate Extended-release Tablets USP 300 mg needs USP Classification 4.

CLINICAL PHARMACOLOGY: Preclinical studies have shown that lithium alters sodium transport in nerve and muscle cells and effects a shift toward intracellular metabolism of catecholamines, but the specific biochemical mechanism of lithium action in man is unknown.

INDICATIONS AND USAGE: Lithium carbonate extended-release tablets are indicated in the treatment of manic episodes of Bipolar Disorder, Bipolar Disorder, Manic (DSM-IV) is equivalent to Manic Depressive illness, Manic, either alone or as an adjuvant therapy (see DOSAGE AND ADMINISTRATION).

In Clinical studies of bipolar disorder, lithium carbonate extended-release tablets are also indicated as a maintenance treatment for individuals with a diagnosis of Bipolar Disorder. Maintenance therapy reduces the frequency of manic episodes and increases the intensity of those episodes which occur.

Typical symptoms of mania include pressure of speech, motor hyperactivity, restlessness, need for sleep, flight of ideas, grandiosity, altered judgment, aggressiveness and possibility hostility. When given to a patient experiencing a manic episode, lithium may produce a normalization of symptomatology within 1 to 3 weeks.

WARNING: Lithium Toxicity: Lithium toxicity is closely related to serum lithium concentrations and can occur at doses close to therapeutic concentrations (see DOSAGE AND ADMINISTRATION).

Outpatients and their families should be warned that the patient must discontinue lithium therapy and contact his physician if such clinical signs of lithium toxicity as diarrhea, vomiting, tremors, mild alopecia, shivering or muscular weakness occur.

Lithium should not be given to patients with significant renal or cardiovascular disease, severe dehydration, dehydration, sodium depletion, and to patients receiving diuretics, or antidepressants converting enzymes (ACE) inhibitors, since the risk of lithium toxicity is very high in such patients. If the psychiatric indication is life threatening and if such a patient fails to respond to other measures, lithium treatment may be undertaken with extreme caution, including daily serum lithium determinations and adjustment to the usually new dose ordinarily tolerated by these individuals. In such instances, hospitalization is a necessity.

UNMASKING OF BRUGADA SYNDROME: There has been post-marketing reports of a possible association between treatment with lithium and the unmasking of Brugada Syndrome. Brugada Syndrome is a disorder characterized by abnormal electrocardiographic (ECG) findings and a risk of sudden death. Lithium should generally be avoided in patients with Brugada Syndrome or those suspect of having Brugada Syndrome. Consultation with a cardiologist is recommended if: (1) treatment with lithium is under consideration for patients suspected of having Brugada syndrome or patients who have risk factors for Brugada Syndrome, e.g., unexplained syncope, a family history of sudden unexplained death before the age of 45 years, (2) patients who develop unexplained syncope or palpitations after starting lithium therapy.

Renal Effects: Chronic lithium therapy may be associated with diminution of renal concentrating ability, particularly in the presence of nephropathy, diabetes insipidus, with polyuria and polydipsia. Such patients should be carefully managed to avoid fluid overload and lithium toxicity. This condition is usually reversible when lithium is discontinued.

Morphologic changes with glomerular and interstitial fibrosis and erosion atrophy have been observed in patients on chronic lithium therapy. Morphologic changes have also been seen in manic-depressive patients never exposed to lithium. The relationship of these functional and morphologic changes and their association with lithium therapy have not been established.

Kidney function should be assessed prior to and during lithium therapy. Routine urinalysis and other tests may be used to evaluate tubular function (e.g., urine specific gravity or sodium following a period of water deprivation or 24-hour urine volume) and glomerular function (e.g., serum creatinine or creatinine clearance). During lithium therapy, progressive or sudden changes in renal function, even within the normal range, indicate the need for reevaluation of treatment.

Encephalopathic Syndrome: An encephalopathic syndrome characterized by weakness, lethargy, fever, tremor, confusion and extrapyramidal symptoms, hyperreflexias, elevated serum amylases, BUN and BFG has occurred in a few patients treated with lithium plus a neuroleptic, most notably haloperidol. In some instances, the syndrome was followed by irreversible brain damage. Because of possible causal relationship between these events and the concurrent administration of lithium and neuroleptics, patients receiving such combined therapy or patients with organic brain syndrome or other CNS impairment should be monitored closely for early evidence of neurologic toxicity and treatment discontinued promptly if such signs appear. This encephalopathic syndrome may be similar to the same as Neuroleptic Malignant Syndrome (NMS).

Concomitant use with Neuroleptic Blocking Agents: Lithium may potentiate the effects of neuroleptic blocking agents. Therefore, neuroleptic blocking agents should be given with caution to patients receiving lithium.

Usage in Pregnancy: Adverse effects on labor in rats, embryo viability in vivo and metabolism in vitro of cubital hair and human spontaneous hair have been attributed to lithium, as have teratogenicity in subhuman primates and sheep given in utero.

In humans, lithium may cause fetal harm when administered to a pregnant woman. Data from lithium births suggests an increase in cardiac and other anomalies, especially Ectopia Nervi. If this drug is used in women of childbearing potential, or during pregnancy, or if a patient becomes pregnant while taking this drug, the patient should be apprised by their physicians of the potential hazard to the fetus.

Usage in Nursing Mothers: Lithium is excreted in human milk. Nursing should not be undertaken during lithium therapy except in rare and unusual