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Brand Name : **AGOLITHO TABLETS** **Generic Name** : Lithium Carbonate Tablets BP 400 mg		2021
Module 1 **1.5**	Administrative Information and Product Information Product Information	**Confidential**

1.5 PRODUCT INFORMATION

1.5.1 Prescribing information (Summary of products characteristics)

SUMMARY PRODUCT CHARACTERISTICS

1. Name of drug product:

AGOLITHO TABLETS (Lithium Carbonate Tablets BP 400 mg)

2. Qualitative and Quantitative Composition:

Each film coated tablet contains: Lithium Carbonate BP 400 mg

3. Pharmaceutical form:

White, circular, biconvex film coated tablets.

4. Clinical particulars:

4.1 Therapeutic Indications:

As many adverse effects are **dose** related the lowest effective dose of lithium should be used. The therapeutic range for prophylaxis is between 0.6–0.8 mmol/L and in acute treatment is 0.8–1.2 mmol/L. If available, refer to the person's 'lithium history' of response and adverse effects for a guide to management.
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4.2 Posology and Method of Administration:

Take this medicine by mouth,
Swallow the tablets whole. Do not crush or chew them,
The tablets can be broken in half. Take your medicine at the same times every day.
If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

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Adult weight about 70 kg.
The usual starting dose is between 400 mg to 1,200 mg each day.
Elderly and adults weighing under 50 kg
The usual starting dose is between 200 mg to 400 mg each day.
Your doctor may decide to increase this dose by 200 mg to 400 mg every 3 to 5 days.
Increasing the dose is usual, But do not do this unless your doctor tells you to do.

Method of administration : Oral.

4.3 Contraindications:

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 may be encountered at serum lithium concentrations below 1.5 mEq/L. Mild to moderate adverse reactions may occur at concentrations from 1.5 to 2.5 mEq/L, and moderate to severe reactions may be seen at concentrations from 2.0 mEq/L and above.

Fine hand tremor, polyuria, and mild thirst may occur during initial therapy for the acute manic phase and may persist throughout treatment. Transient and mild nausea and general discomfort may also appear during the first few days of lithium administration.

These side effects usually subside with continued treatment or with a temporary reduction or cessation of dosage. If persistent, a cessation of lithium therapy may be required. Diarrhea, vomiting, drowsiness, muscular weakness, and lack of coordination may be early signs of lithium intoxication, and can occur at lithium concentrations below 2.0 mEq/L. At higher concentrations, giddiness, ataxia, blurred vision, tinnitus, and a large output of dilute urine may be seen. Serum lithium concentrations above 3.0 mEq/L may produce a complex clinical picture involving multiple organs and organ systems. Serum lithium concentrations should not be permitted to exceed 2.0 mEq/L during the acute treatment phase.The following reactions have been reported and appear to be related to serum lithium concentrations, including concentrations within the therapeutic range:

Central Nervous System: tremor, muscle hyperirritability (fasciculations, twitching, clonic movements of whole limbs), hypertonicity, ataxia, choreoathetotic movements, hyperactive deep tendon reflex, extrapyramidal symptoms including acute dystonia, cogwheel rigidity, blackout spells, epileptiform seizures, slurred speech, dizziness, vertigo, downbeat nystagmus, incontinence of urine or feces, somnolence, psychomotor retardation, restlessness, confusion, stupor, coma, tongue movements, tics, tinnitus, hallucinations, poor memory, slowed intellectual functioning, startled response, worsening of organic brain syndromes. Cases of Pseudotumorcerebri (increased intracranial pressure and papilledema) have been

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reported with lithium use. If undetected, this condition may result in enlargement of the blind spot, constriction of visual fields and eventual blindness due to optic atrophy. Lithium should be discontinued, if clinically possible, if this syndrome occurs.

Cardiovascular:cardiac arrhythmia, hypotension, peripheral circulatory collapse, bradycardia, sinus node dysfunction with severe bradycardia (which may result in syncope), Unmasking of Brugada Syndrome .

Gastrointestinal: anorexia, nausea, vomiting, diarrhea, gastritis, salivary gland swelling, abdominal pain, excessive salivation, flatulence, indigestion.

Genitourinary: glycosuria, decreased creatinine clearance, albuminuria, oliguria, and symptoms of nephrogenic diabetes insipidus including polyuria, thirst and polydipsia.

Dermatologic: drying and thinning of hair, alopecia, anesthesia of skin, acne, chronic folliculitis, xerosis cutis, psoriasis or its exacerbation, generalized pruritus with or without rash, cutaneous ulcers, angioedema.

Autonomic Nervous System: blurred vision, dry mouth, impotence/sexual dysfunction.

Thyroid Abnormalities: euthyroid goiter and/or hypothyroidism (including myxedema) accompanied by lower T3 and T4. Iodine uptake may be elevated. Paradoxically, rare cases of hyperthyroidism have been reported.

EEG Changes: diffuse slowing, widening of frequency spectrum, potentiation and disorganization of background rhythm.

EKG Changes: reversible flattening, isoelectricity or inversion of T-waves.

Miscellaneous : fatigue, lethargy, transient scotomata, exophthalmos, dehydration, weight loss, leucocytosis, headache, transient hyperglycemia, hypercalcemia, hyperparathyroidism, albuminuria, excessive weight gain, edematous swelling of ankles or wrists, metallic taste, dysgeusia/taste distortion, salty taste, thirst, swollen lips, tightness in chest, swollen and/or painful joints, fever, polyarthralgia, and dental caries.

Some reports of nephrogenic diabetes insipidus, hyperparathyroidism, and hypothyroidism which persist after lithium discontinuation have been received.

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4.4 Special Warnings and Precautions for Use :

Lithium toxicity is closely related to serum lithium concentrations and can occur at doses close to therapeutic concentrations 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, tremor, mild ataxia, drowsiness, or muscular weakness occur.

The risk of lithium toxicity is increased in patients with significant renal or cardiovascular disease, severe debilitation or dehydration, or sodium depletion, and for patients receiving prescribed medications that may affect kidney function, such as angiotensin converting enzyme inhibitors (ACE inhibitors), angiotensin receptor blockers (ARBs), diuretics (loops and thiazides) and NSAIDs. For these patients, consider starting with lower doses and titrating slowly while frequently monitoring serum lithium concentrations and signs of lithium toxicity.

"This product contains lactose."

4.5 Pregnancy and Lactation:

Adverse effects on nidation in rats, embryo viability in mice, and metabolism *in vitro* of rat testis and human spermatozoa have been attributed to lithium, as have teratogenicity in submammalian species and cleft palate in mice.

In humans, lithium may cause fetal harm when administered to a pregnant woman. Data from lithium birth registries suggest an increase in cardiac and other anomalies, especially Ebstein's anomaly. 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

4.6 Overdose:

The toxic concentrations for lithium are close to the therapeutic concentrations. It is therefore important that patients and their families be cautioned to watch for early toxic symptoms and to discontinue the drug and inform the physician should they occur. (Toxic symptoms are listed in detail under

5. Pharmacological properties:

5.1 Pharmacodynamic properties:

Lithium Carbonate is a prescription medicine used to treat the symptoms of Bipolar Disorder. Lithium Carbonate may be used alone or with other medications.

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Lithium Carbonate belongs to a class of drugs called Bipolar Disorder Agents.It is not known if Lithium Carbonate is safe and effective in children younger than 7 years of age.

5.2 Pharmacokinetic Properties:

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

6. Pharmaceutical particulars:

6.1 List of Excipients:

Lactose	BP
Maize starch	BP
Sodium Starch Glycolate	BP
Colloidal silicon dioxide	BP
Methyl Paraben sodium	BP
Propyl Paraben sodium	BP
Magnesium stearate	BP
Purified talc	BP
Polyplasdone XL-10	USP
Cross Carmellose sodium	BP
Sodium Lauryl sulphate	BP
Colour instacoat sol White 010	INH
Methylene Dichloride	BP
Iso Propyl alcohol	BP

6.2 Incompatibilities:
None Reported

6.3 Shelf-Life:
36 months from the date of manufacture.

6.4 Special Precautions for Storage:
Store under normal storage conditions (15°C to 30°C).
Protect from light.

6.5 Nature and Contents of Container:

100 tablets are packed in a primary packaging material of Poly Bag having dimension 4 X 6 inches & such poly bag is packed in a jar.
Material of construction of primary packaging material Poly Bag (4" X 6") is attached.

6.6 Special precautions for disposal:
None reported.

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7. **Registrant:**
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8. **Manufacturer:**
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9. **Date of revision of the text : 22/03/2022**