



LITHIUM ORAL SOLUTION USP

8 mEq per 5 ml



NDC	Description	Strength	Package Size
72888-0172-46	Lithium Oral solution	8mEq /5 mL	500 mL

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Lithium Oral Solution USP 8 mEq per 5 mL

Advagen Pharma Ltd.

DESCRIPTION

Each 5 mL of solution for oral administration contains lithium ion (Li⁺), 8 mEq (equivalent to amount of lithium in 300 mg of lithium carbonate), alcohol 0.3% v/v and the following other inactive ingredients: citric acid, purified water, artificial cherry flavor, sodium benzoate and sorbitol solution. May also contain sodium hydroxide for pH adjustment.

The empirical formula for Lithium Citrate is C₆H₅Li₃O₇; molecular weight 209.93. Lithium acts as an antimanic.

INDICATIONS AND USAGE

Lithium is a mood-stabilizing agent indicated as monotherapy for the treatment of bipolar I disorder:

Treatment of acute manic and mixed episodes in patients 7 years and older

Maintenance treatment in patients 7 years and older

DOSAGE FORMS & STRENGTHS

Each 5 mL of clear, colorless lithium oral solution USP contains 8 mEq lithium ion (Li⁺) (equivalent to the amount of lithium in 300 mg of lithium carbonate).

DOSAGE AND ADMINISTRATION

1 Pre-treatment Screening

Before initiating treatment with lithium, renal function, vital signs, serum electrolytes, and thyroid function should be evaluated. Concurrent medications should be assessed, and if the patient is a woman of childbearing potential, pregnancy status and potential should be considered.

2 Recommended Dosage

Patient Group	Formulation	Starting Dose	Dose Titration	Acute Goal		Maintenance Goal	
				Serum Level	Usual Dose	Serum Level	Usual Dose
Adult and Pediatric Patients over 30 kg	Liquid	8 mEq (5 mL) three times daily	8 mEq (5 mL) every three days	0.8 to 1.2 mEq/L	16 mEq (10 mL) two to three times daily	0.8 to 1.0 mEq/L	8 to 16 mEq (5 to 10 mL) two to three times daily
							16 to 40 mEq (10 to 25 mL) in divided doses daily
Pediatric Patients 20 to 30 kg	Liquid	8 mEq (5 mL) twice daily	8 mEq (5 mL) weekly				

Each 5 mL of Lithium Oral Solution contains 8 mEq of lithium ion (Li⁺) which is equivalent to the amount of lithium in 300 mg of lithium carbonate.

3 Serum Lithium Monitoring

Blood samples for serum lithium determination should be drawn immediately prior to the next dose when lithium concentrations are relatively stable (i.e., 12 hours after the previous dose). Total reliance must not be placed on serum concentrations alone. Accurate patient evaluation requires both clinical and laboratory analysis

In addition to regular monitoring of serum lithium concentrations for patients on maintenance treatment, serum lithium concentrations should be monitored after any change in dosage, concurrent medication (e.g., diuretics, non-steroidal anti-inflammatory drugs, renin-angiotensin system antagonists, or metronidazole), marked increase or decrease in routinely performed strenuous physical activity (such as an exercise program) and in the event of a concomitant disease

Patients abnormally sensitive to lithium may exhibit toxic signs at serum concentrations that are within what is considered the therapeutic range. Geriatric patients often respond to reduced dosage, and may exhibit signs of toxicity at serum concentrations ordinarily tolerated by other patients

4 Dosage Adjustments during Pregnancy and the Postpartum Period

If the decision is made to continue lithium treatment during pregnancy, monitor serum lithium concentrations and adjust the dosage as needed in a pregnant woman because renal lithium clearance increases during

pregnancy. Avoid sodium restriction or diuretic administration. To decrease the risk of postpartum lithium intoxication, decrease or discontinue lithium therapy two to three days before the expected delivery date to reduce neonatal concentrations and reduce the risk of maternal lithium intoxication due to the change in vascular volume which occurs during delivery. At delivery, vascular volume rapidly decreases and the renal clearance of lithium may decrease to pre-pregnancy concentrations. Restart treatment at the preconception dose when the patient is medically stable after delivery with careful monitoring of serum lithium concentrations

5 Dosage Adjustments for Patients with Renal Impairment

Start patients with mild to moderately impaired renal function (creatinine clearance 30 to 89 mL/min evaluated by Cockcroft-Gault) with dosages less than those for patients with normal renal function. Titrate slowly while frequently monitoring serum lithium concentrations and monitoring for signs of lithium toxicity. Lithium is not recommended for use in patients with severe renal impairment (creatinine clearance less than 30 mL/min evaluated by Cockcroft-Gault)

OVERDOSAGE

The toxic concentrations for lithium (≥ 1.5 mEq/L) are close to the therapeutic concentrations. At lithium concentrations greater than 3 mEq/L, patients may progress to seizures, coma, and irreversible brain damage.

MEDICATION GUIDE/FAQ'S

What is the most important information I should know about Lithium Oral Solution?

Lithium Oral Solution can cause serious side effects, including:

too much lithium in your blood (lithium toxicity). Lithium toxicity that can cause death may happen even if the lithium level in your blood is close to the right level for you. Your healthcare provider will need to monitor your blood levels of lithium to find the best dose for you. Take your Lithium Oral Solution exactly as your healthcare provider tells you to take it. **Stop taking Lithium Oral Solution and call your healthcare provider right away if you have any symptoms of lithium toxicity including:**

- abnormal heartbeat
- vomiting
- diarrhea
- drowsiness
- weak muscles
- blurred vision
- clumsiness
- ringing in your ears
- muscle twitching

Other symptoms may include:

- lightheadedness
- confusion
- bloating
- mood changes
- slurred speech
- breathing problems
- seizure
- coma

Who should not take Lithium Oral Solution?

Do not take Lithium Oral Solution if you are allergic to Lithium or any of the ingredients in Lithium Oral Solution

What should I tell my healthcare provider before taking Lithium Oral Solution?

Before taking Lithium Oral Solution, tell your healthcare provider if you:

- have kidney problems
- have heart problems
- have breathing problems
- have thyroid problems
- are pregnant or plan to become pregnant. Lithium Oral Solution may harm your unborn baby.
- are breastfeeding or plan to breastfeed. Lithium can pass into your breastmilk and may harm your baby. You should not breastfeed during treatment with Lithium Oral Solution.

Tell your healthcare provider about all the medicines you take, including prescription, over-the-counter medicines, vitamins, and herbal supplements. Using Lithium with certain other medicines may affect each other causing possible side effects. Lithium may affect the way other medicines work, and other medicines may affect how Lithium works.

Especially tell your healthcare provider if you take:

MAOIs	selective serotonin reuptake inhibitors (SSRIs)
serotonin norepinephrine reuptake inhibitors called (SNRIs)	medicines used to treat migraine headaches called triptans
tricyclic antidepressants	fentanyl
antipsychotic medicines	tramadol
tryptophan	buspirone

St John's Wort

Your healthcare provider can tell you if it is safe to take Lithium with your other medicines. Do not start or stop any medicines while taking Lithium without talking to your healthcare provider first.

Know the medicines you take. Keep a list of your medicines to show your healthcare provider and pharmacist when you get a new medicine.

How should I store Lithium Oral Solution?

Store Lithium Oral solution at room temperature, between 68°F to 77°F (20°C to 25°C).

How should I take Lithium Oral Solution?

Take your Lithium Oral Solution exactly as prescribed by your healthcare provider.

If you take too much Lithium Oral Solution, call your healthcare provider or poison control center, or go to the nearest hospital emergency room right away. In case of poisoning, call your poison control center at 1-800-222-1222.

What should I avoid while taking Lithium Oral Solution?

Do not drive, operate heavy machinery, or do other dangerous activities when you start taking Lithium Oral Solution, when your dose is changed, or until you know how Lithium affects you. Lithium Oral Solution can make you sleepy. Talk to your healthcare provider about these activities.

Avoid becoming overheated or dehydrated during exercise and in hot weather. Follow your healthcare provider instructions about the type and amount of liquids you should drink. In some cases, drinking too much liquid can be as unsafe as not drinking enough.

Do not change the amount of salt in your diet. Changing the amount of salt in your diet could change the amount of Lithium in your blood.

What are the possible side effects of Lithium Oral Solution? Lithium Oral Solution may cause serious side effects, including:

- kidney problems
- low levels of sodium (salt) in your blood (hyponatremia)
- neurological problems.
- serotonin syndrome Symptoms of serotonin syndrome include: • agitation • seeing things that are not there • confusion • coma • rapid pulse • high or low blood pressure • dizziness • sweating • flushing • fever • tremors • stiff muscles • muscle twitching • become unstable • seizures • nausea • vomiting • diarrhea
- thyroid problems • high calcium levels in your blood • heart problems (hypercalcemia)
- increased pressure in the brain and swelling in the eye (pseudotumor cerebri)

The most common side effects of Lithium, include:

Adults with manic or mixed episodes of bipolar I disorder:

- hand trembling
- excessive urination
- increased thirst
- nausea
- general discomfort when you start treatment

Children 7 to 17 years of age with manic or mixed episodes of bipolar I disorder:

- excessive urination
- thyroid problems
- hand trembling
- excessive thirst
- dizziness
- rash
- difficulty walking
- decreased appetite
- blurred vision
- nausea
- vomiting

Keep Lithium Oral Solution and all medicines out of the reach of children.

For more information about Lithium Oral Solution contact Advagen Pharma Ltd, at **866-488-0312**

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