MEDICATION GUIDE

Lithium (lith' ee um) Oral Solution, USP

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:**

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

  Other symptoms may include:

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

What is Lithium Oral Solution?

Lithium Oral Solution is prescription medicines called mood-stabilizing agents used alone (monotherapy) for:

- the acute (short-term) treatment of people 7 years of age and older with manic and mixed episodes that happen with bipolar I disorder.
- maintenance treatment of bipolar I disorder in people 7 years of age and older.

It is not known if Lithium Oral Solution is safe and effective in children under 7 years of age with bipolar I disorder.

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. See the end of this Medication Guide for a complete list of 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. Talk to your healthcare provider about the best way to feed your baby if you take Lithium.

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 (SNRIs)
- medicines used to treat migraine headaches called triptans
- tricyclic antidepressants
- fentanyl
- antipsychotic medicine
- tramadol
- tryptophan buspirone
- 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 take Lithium Oral Solution?

- Take your Lithium Oral Solution exactly as prescribed by your healthcare provider.
- Your healthcare provider will do certain blood tests before starting and during treatment with Lithium Oral Solution.
- Your healthcare provider may change your dose if needed. **Do not** change your dose on your own.
- **Do not** double your dose if a dose is missed. Talk with your healthcare provider if you miss a dose.
- **Do not** stop taking Lithium Oral Solution suddenly without talking to your healthcare provider.
- Your healthcare provider may change your Lithium Oral Solution dose to make sure you are taking the dose that is right for you.
- 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?

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

Lithium Oral Solution may cause serious side effects, including:

- **kidney problems.** People who take Lithium Oral Solution may have to urinate often (polyuria) and have other kidney problems that may affect how their kidneys work. These problems can happen within a few weeks of starting to take Lithium Oral Solution or after taking Lithium Oral Solution for a long time.
- **low levels of sodium (salt) in your blood (hyponatremia).** Lithium can cause you to lose sodium. Talk to your healthcare provider about your diet and how much fluid you are drinking when starting Lithium Oral Solution. If you have been sweating more than usual or have had diarrhea, you may need extra salt and more fluids. Talk to your healthcare provider if this happens.
- **neurological problems.** People who take Lithium Oral Solution with certain other medicines called antipsychotics may have symptoms such as weakness, tiredness, fever, tremors, and confusion. Talk to your healthcare provider if this happens. Ask if you are not sure about the medicines you take.
- **serotonin syndrome.** A potentially life-threatening problem called serotonin syndrome can happen when you take Lithium Oral Solution while you take certain medicines called serotonergic and MAOIs. Symptoms of serotonin syndrome include:

  o agitation o seeing things that are not there o confusion
  o coma o rapid pulse o high or low blood pressure
  o dizziness o sweating o flushing
  o fever o tremors o stiff muscles
  o muscle twitching o become unstable o seizures
  o nausea o vomiting o diarrhea

- **thyroid problems.**
- **high calcium levels in your blood (hypercalcemia) and changes in your parathyroid gland (hyperparathyroidism)** that may not go away when you stop taking Lithium.
- **heart problems.** People who take Lithium may find out they also have a heart problem called Brugada Syndrome. People who have unexplained fainting or who have a family history of sudden unexplained death before 45 years of age may have Brugada Syndrome and not know it. If you faint or feel abnormal heartbeats, talk to your healthcare provider right away.
- **increased pressure in the brain and swelling in the eye (pseudotumor cerebri)** that can cause vision problems or blindness. If you have severe headaches behind your eyes, ringing in the ears, blurred vision, double vision, or brief periods of blindness, talk to your health care provider right away.

The most common side effects of Lithium, include:

- Adults with manic or mixed episodes of bipolar I disorder:
  - o hand trembling
  - o excessive urination
  - o increased thirst
  - o nausea
  - o general discomfort when you start treatment
- Children 7 to 17 years of age with manic or mixed episodes of bipolar I disorder:
  - o excessive urination
  - o thyroid problems
  - o hand trembling
  - o excessive thirst
  - o dizziness
  - o rash
  - o difficulty walking
  - o decreased appetite
  - o blurred vision
  - o nausea
  - o vomiting

These are not all the possible side effects of Lithium.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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). [See USP Controlled Room Temperature.]

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

General information about the safe and effective use of Lithium Oral Solution.
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Lithium Oral Solution for a condition for which it was not prescribed. Do not give Lithium Oral Solution to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about Lithium Oral Solution that is written for healthcare professionals.

For more information about Lithium Oral Solution, please , call Advagen Pharma Ltd, at 866-488-0312.

What are the ingredients in Lithium Oral Solution?

Active ingredient: Trilithium Citrate Tetrahydrate

Inactive ingredients: alcohol 0.3%, citric acid, purified water, artificial cherry flavor, sodium benzoate and sorbitol solution.

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Advagen Pharma Ltd.,
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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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