



LITHIUM

EACH TABLET CONTAINS:
Lithium Carbonate, USP 300mg
Product meets USP Drug Release Test 1.

DOSE AND ADMINISTRATION:
See accompanying insert for complete directions for use.

WARNINGS: See package insert. Dispense in a tight, child-resistant container (USP). Store between 59°-86°F (15°-30°C). Protect from moisture.

Manufactured By:
ANI Pharmaceuticals, Inc.
Baltimore, Maryland 21244

For:
Noven Therapeutics, Inc. 1171
Millsboro, DE 19966-0001 06/08

100 Tablets NDC 68968-4492-1

LITHOBID®
(Lithium Carbonate, USP)
Extended-Release Tablets
300 mg
Rx only

Noven Therapeutics

LOT: EXP.:

8
68968-4492-1
3



PRESCRIPTION ONLY MEDICINE
KEEP OUT OF REACH OF CHILDREN

LITHIUM CARBONATE 250mg
LITHIUM CARBONATE BP CAPSULES

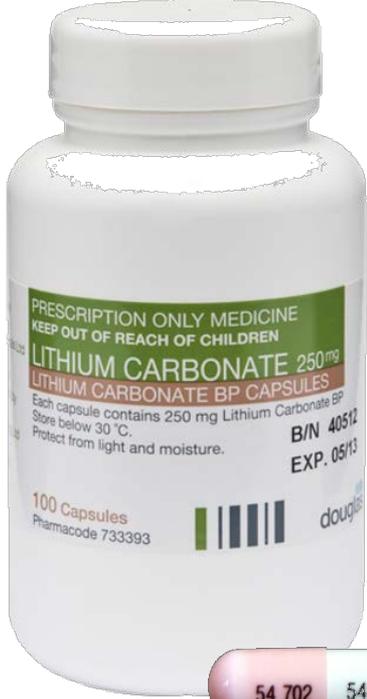
Each capsule contains 250 mg Lithium Carbonate BP.
Store below 30 °C.
Protect from light and moisture.

B/N 40512
EXP. 05/13

100 Capsules
Pharmacode 733393

douglas

54 702 54 702



450 mg
Eskalith CR®
lithium carbonate
Controlled Release tablets

ESKALITH
SR



BRAND NAME: ESKALITH & LITHOBID



Lithium

History

Lithium, a naturally-occurring substance, discovered in 1817, was noticed to have mood stabilizing properties in the late 1800s when doctors were using it to treat gout.

It was Australian psychiatrist John Cade who, in 1949, published the first paper on the use of lithium in the treatment of acute mania.

Texas study:

Using data for 27 Texas counties from 1978-1987, it is shown that the incidence rates of suicide, homicide, and rape are significantly higher in counties whose drinking water supplies contain little or no lithium than in counties with water lithium levels ranging from 70-170 micrograms/L; the differences remain statistically significant (p less than 0.01) after corrections for population density.

The corresponding associations with the incidence rates of robbery, burglary, and theft were statistically significant with p less than 0.05. These results suggest that lithium has moderating effects on suicidal and violent criminal behavior at levels that may be encountered in municipal water supplies.

These results suggest that lithium at low dosage levels has a generally beneficial effect on human behavior, which may be associated with the functions of lithium as a nutritionally-essential trace element.

Lithium



Pharmacodynamics

study of what a drug does to the body

Lithium acts on the central nervous system.



Lithium interferes with the production and uptake of chemical messengers by which nerves communicate with each other (neurotransmitters).

Lithium also affects the concentrations of tryptophan and serotonin in the brain.

It also increases the production of white blood cells in the bone marrow.

Lithium

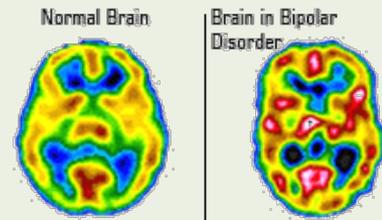


Pharmacology

science of drug action on biological systems

One of the most widely used and studied medications for treating bipolar disorder

Helps reduce the severity and frequency of mania
Also, helps relieve or prevent bipolar depression



Exactly how lithium works to stabilize an individual's mood is unknown, but it is thought to help strengthen nerve cell connections in brain regions that are involved in regulating mood, thinking and behavior.

Lithium's effects usually begin within 1 week of starting treatment, and the full effect is seen by 2 to 3 weeks.

Lithium



Side Effects

Common Side Effects

- Mild tremors
- Loss of appetite & mild thirst
- Weight gain/loss
- Excessive saliva in mouth
- Thin/brittle fingernails or hair
- Itching/Rashes
- Mild joint, muscle and stomach pain
- Unusual discomfort in cold temperatures



Lithium

Severe Side Effects

- Lithium toxicity – Early signs (nausea, vomiting, diarrhea, drowsiness, muscle weakness, tremor, lack of coordination, blurred vision or ringing in ears)

Be aware that lithium toxicity symptoms are similar to flu-like symptoms!

- Extreme thirst
- Frequent urination
- Eye pain or vision problems
- Restless muscle movements in eyes, tongue, jaw or neck
- Painful, cold or discolored fingers/toes
- Lightheadedness / dizziness
- Fainting
- Fast, slow, irregular heartbeat
- Hallucinations
- Seizures
- Muscle stiffness



(Stop use of lithium immediately if these side effects are seen & contact doctor)



Associated Risks

The primary risk in taking lithium is *lithium toxicity* and *retention*.

Lithium carbonate may impair mental and physical abilities that may cause:

- Scarring of lungs (interstitial fibrosis)
- Kidney shrinkage (nephron atrophy)
- encephalopathic syndrome -> irreversible brain damage
 - ↳ (characterized by neurotoxicity in the setting of posterior cerebral edema)



Chronic lithium therapy may be associated with diabetes insipidus, with polyuria¹ and polydipsia².

This condition is usually reversible when lithium is discontinued.

Studies show that lithium can significantly reduce suicide risk.

1. polyuria – production of abnormally large volumes of dilute urine
2. polydipsia – excessive thirst

Lithium





Lithium Toxicity

Are you aware of the warning signs?

If a person's lithium levels get too high this can be potentially dangerous and will produce some unpleasant and severe side effects that can be fatal:

Warning signs of lithium toxicity:

- Dehydration
- Lack of appetite
- Diarrhoea
- Vomiting
- Blurred vision

More severe lithium excess can lead to:

- A marked tremor (shakiness)
- Unsteadiness
- Slurred speech
- Drowsiness
- Confusion

As the lithium level gets even higher the person may experience:

- Muscles twitches
- Very severe drowsiness and confusion
- Fits
- Unconsciousness

Any illness leading to dehydration can increase the level of lithium in the blood!

If a person on lithium starts to experience any of the above symptoms - even the mild ones - it is **ESSENTIAL** they see a **DOCTOR IMMEDIATELY**.

For further information on lithium therapy and how to manage a person who has been prescribed lithium please visit our website:
www.leeds.nhs.uk/lithium



Contraindications

A specific situation in which a drug, procedure, or surgery should not be used because it may be harmful to the patient.

Lithium should generally not be given to patients with (who) ...

- Brugada syndrome
- Addison's disease
- significant renal or cardiovascular disease
- severe debilitation, dehydration or sodium depletion
- untreated hypothyroidism
- are taking diuretics
- are breast-feeding

Lithium



Pregnancy Risks



Not a major national harming factor in embryos, according to recent studies, but the use of lithium in the first trimester has been associated with congenital defects and Ebstein's anomaly.

Lithium toxicity has been reported in neonates whose mothers took lithium during pregnancy .

Lithium toxicity in breast-fed infants, including cyanosis¹, electrocardiogram abnormalities and hypotonia² have also been reported.

Lithium is excreted into and accumulates in human milk. Lithium is contraindicated during breast-feeding.

It should only be given during pregnancy when there are no alternatives and benefit outweighs risk.

1. Cyanosis – bluish discoloration of skin from poor circulation/inadequate oxygenation of blood
2. Hypotonia – (Floppy Baby Syndrome) state of low muscle tone

Lithium



Potential Dangers



Alcohol:

- Drinking alcohol may increase nervous system side effects such as dizziness, drowsiness and difficulty concentrating.

Caffeine

- Using caffeine together with lithium may increase the effects of caffeine.

General Applications:

- Lithium can cause side effects that may impair your thinking or reactions. Be careful if you drive or do anything that requires you to be awake and alert.

Excessive Heat:

- People taking lithium should avoid coming in contact with extreme heat, as it may cause excessive perspiration and result in considerable running down of water and salt, thereby giving rise to lithium toxicity. If you are using lithium, you also need to stay away from sauna baths.

Lithium



Potential Dangers continued

Other prescriptions: (Some MEDS MAY INTERACT with lithium!)

There are over 1062 drugs (5649 brand and generic names) that are known to interact with lithium.

Always be cautious with drug interactions and always remind doctors of the client's use of lithium.

Listed below is a link to the site that has all medications that interact with lithium



<http://www.drugs.com/drug-interactions/lithium-index.html>

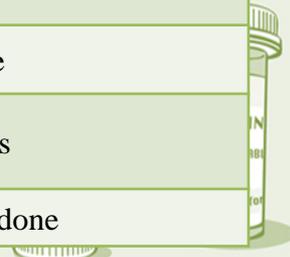
NOTE: Some drugs have multiple combinations, such as acetaminophen and hydrozine, with lithium. Please be aware of the combos that lithium can interact with.

Lithium



Common Meds, among APS clients, interacting with lithium

<u>Severity</u>		<u>Risks</u>
<u>High</u> (153 meds)	<u>Moderate</u> (834 meds)	
	•Aripiprazole (Abilify)	Increase effects of aripiprazole
	•Olanzapine	Increases effects of olanzapine
<ul style="list-style-type: none"> •Duloxetine (Cymbalta) •Fluoxetine (Prozac) •Sertraline (Zoloft) •Citalopram •Venlafaxine (Effexor) •Fluvoxamine (Luvox) •Trazodone 		<p>Increase risk of rare/serious condition, serotonin syndrome</p> <p>Severe cases may result in coma/death</p>
	<ul style="list-style-type: none"> •Clonazepam (Klonopin) •Lamotrigine (Lamictal) •Cetirizine •Diphenhydramine (Benadryl) •Divalproex sodium (Depakote) •Hydroxyzine 	<p>Increase side effects such as dizziness, drowsiness , difficulty concentrating and impairment in thinking and judgment</p>
•Escitalopram	•Quetiapine (Seroquel)	Increase risk of irregular heart rhythm
<ul style="list-style-type: none"> •Bupropion •Tramadol 		Increases risk of seizures
	•Clonidine	Lowers blood pressure
<ul style="list-style-type: none"> •Hydrochlorothiazide •Haloperidol (Haldol) 	•Ibuprofen	Increases lithium levels
	•Risperidone (Risperdal)	Increases effects of risperidone



Laboratory Monitoring

A battery of laboratory tests including a complete blood count, tests for serum, creatinine and electrolytes, hormones, and urinalysis must be conducted before prescribing this medication, and thereafter repeated on a regular basis so as to provide adequate monitoring of lithium blood levels.



To ensure that this medication is not causing harmful effects, kidney function will need to be tested on a regular basis. Measuring creatinine in blood serum is a test for kidney function. If creatinine levels are high it may mean that the kidneys are not fully functional. Since kidney function is essential to clearing lithium from the system (so as to avoid lithium toxicity) this test is particularly important before prescribing lithium to a patient.

To avoid lithium toxicity, the patient must undergo regular blood monitoring to measure levels of lithium and make sure that they remain within an acceptable dose range. Blood lithium levels need to be monitored closely and most frequently during the early stages of treatment. However, as treatment stabilizes, blood monitoring can occur as little as every three to six months.



(Self) Administration Instructions

Follow the directions on your prescription label.

Take lithium exactly as it was prescribed for you. Do not take the medication in larger amounts, or take it for longer than recommended by your doctor.

Extended-Release Tablets:

Do not crush, chew, or break an extended-release lithium tablet. Swallow the pill whole.

It is specially made to release medicine slowly in the body. Breaking the lithium pill would cause too much of the drug to be released at one time.

Oral Form:

Measure the liquid form of lithium with a *special dose-measuring spoon or cup*, not a regular table spoon. If you do not have a dose-measuring device, ask your pharmacist for one.

Note: *The taste may be pungent. If the client cannot tolerate the taste, ask pharmacist for mix-ins.*

Drink extra fluids each day to keep from getting dehydrated while you are taking lithium. Dehydration can increase some of the side effects of lithium.

Also, there is a common side effect of upset stomachs and vomiting, that may result from client taking the lithium on an empty stomach. It's best if lithium medication was taken with food.



Lithium



Dosage

Doses of lithium should be individualized on the basis of response to therapy and levels of lithium in your blood.

The dose your doctor recommends may be based on the following:

1) the condition being treated and 2) how you respond to this medication.

The recommended dose of lithium for acute episodes of mania is 600mg, 3 times a day.

The recommended dose of lithium for long-term control and prevention of episodes of mania is 300mg, 3-4 times a day.

Your doctor may occasionally change your dose to make sure you get the best results from lithium.

Lithium



Management & Planning

Note that lithium toxicity is closely related to lithium levels in the blood and can occur at doses close to therapeutic levels.

It is very important to monitor lithium levels while taking the medication. Also, it is important to monitor fluid and salt levels in your diet.

Miss a dose? Call a pharmacist or doctor.

Overdose? Seek emergency medical attention or call the Poison Help line
@ 1-800-222-1222

Changing dose? Consult with a doctor and follow your doctor's instructions about tapering your dose.

Store lithium at room temperature, away from moisture and heat.

Lithium



Nonadherence/Relapse

About a third of patients will relapse, usually into mania rather than depression, in the following few weeks. This is a rebound effect in that patients do not return to the underlying natural history of manic depression but 'rebound' beyond this to a much higher chance of recurrence.

If lithium is stopped gradually over 4–6 weeks then the risk of relapse is less than with sudden cessation and patients return to the risk associated with the natural history and avoid the rebound. However, many doctors would stop the treatment even more slowly, so that any emerging symptoms can be responded to by increasing the dose of lithium again. If a patient is well on lithium there needs to be a very good reason for stopping treatment – manic depression does not go away. If the patient is well it is likely that this is because the treatment is working effectively.

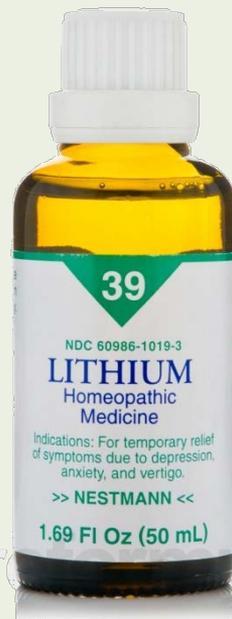


Lithium



Nonadherence/Relapse continued

The liquid form of lithium is known to be clear. To avoid occurrences of lithium being mistaken as water or as another clear substance, use food-coloring to distinguish lithium from other substances.



Lithium



Diet/Exercise

Food interactions: This medication does not interact with food, except in monitoring salt levels in diet.

Do not change the amount of salt that you consume in your diet. Changing your intake of salt could alter the amount of lithium in your blood.

Smoking: Undergoing treatment with lithium may make you more susceptible to nicotine. It's best avoided.

If smoking, there may be a possible indirect effect. Smoking increases caffeine metabolism and significant changes in amount of caffeine may affect serum lithium levels.

Smoking cessations may indirectly change lithium excretion. Be sure to check levels especially if deterioration is evident.

Taking this medication can make it easier for you to become dehydrated, especially if you have vomiting or diarrhea, if you are outdoors in the sun or if you exercise vigorously or sweat more than usual.

Dehydration can increase the side effects of lithium.

Monitor your fluid levels –
drinking too much liquid can be unsafe as not drinking enough.

Lithium



Additional Resources



Anyone requesting financial services/assistance can call to request a faxed application or download it from the website.

PO Box 1244
Winter Park, FL 32790-1244
Phone : 866-699-8239
Fax: 407-671-7960

<https://www.rxhope.com/PAP/info/PAPList.aspx?drugid=1092&fieldType=drugid>

Note: Lithium is a relatively inexpensive medication, ranging from \$40 and less.

Lithium

