

**Patient package insert according to  
Pharmacist's Regulations (Preparations)-1986**

The medicine can be sold by physician's prescription only

## Licarbium

### 300 mg, Tablets

Each tablet contains: Lithium Carbonate 300 mg (=0.056 g Lithium)

Inactive and allergenic ingredients in the medicine - see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".

**Read the entire leaflet carefully before using this medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

**This medicine is not intended for infants and children younger than 12 years of age.**

**Lithium toxicity is closely related to serum concentrations of Lithium and may occur in doses close to therapeutic concentrations. Before starting treatment verify that equipment is on hand for quick and accurate monitoring of serum concentrations of Lithium.**

#### **1. What is the medicine intended for?**

For treatment of episodes of manic depression.

**Therapeutic group:** Mood-stabilizing agents.

#### **2. Before using the medicine**

**Do not use the medicine if:**

- You are hypersensitive (allergic) to the active ingredient (Lithium Carbonate) or Lithium Citrate or to any of the other ingredients this medicine contains (see section 6 "Additional information").

#### **Special warnings regarding the use of the medicine**

**Before treatment with Licarbium, tell your doctor if:**

- You have kidney problems.
- You have heart problems.
- You have breathing problems.
- You have thyroid gland problems.
- You are pregnant or plan to become pregnant (-see additional information in section 2 "Pregnancy and breastfeeding").
- You are breastfeeding or are planning to breastfeed (-see additional information in section 2 "Pregnancy and breastfeeding").
- During the period of treatment with **Licarbium**, avoid becoming overheated or dehydrated during physical activity and in hot weather. Follow your doctor's instructions about the type and amount of liquids you should drink. In certain cases, drinking too much liquid may be as unsafe as not drinking enough liquids.
- Do not change the amount of salt in your diet. Changing the amount of salt intake may change the amount of Lithium Carbonate in your blood.

#### **Children and adolescents:**

This medicine is not intended for infants and children younger than 12 years of age.

#### **Tests and follow up**

Before and/ or during treatment with the medicine, your doctor will request that you take certain blood tests.

#### **Drug interactions:**

**If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** Especially if you are taking:

- Monoamine oxidase inhibitors.
- Serotonin and Norepinephrine reuptake inhibitors.
- Antipsychotic medicines such as: Risperidone, Haloperidol, Thioridazine, Fluphenazine, Chlorpromazine, Perphenazine, Clozapine.
- Selective serotonin reuptake inhibitors.
- Serotonergic medicines such as: Tricyclic antidepressants, Fentanyl, Tramadol, Tryptophan, Buspirone and the Hypericum plant (St. John's Wort).
- Triptans (for treating migraine headaches).
- Diuretics such as: Hydrochlorothiazide, Chlorothiazide, Furosemide.
- Nonsteroidal anti-inflammatory medicines such as: Indomethacin, Ibuprofen, Naproxen.
- Renin-angiotensin system antagonists such as: Lisinopril, Enalapril, Captopril, Valsartan.
- Antibiotics from the Nitroimidazole group such as: Metronidazole.
- Acetazolamide, Urea, products containing derivatives of Xanthine (such as: Theophylline and drinks containing caffeine such as: coffee, tea, cola), Alkalinizing agents such as: Sodium Bicarbonate - may affect blood levels of Lithium Carbonate.
- Methylidopa, Phenytoin, Carbamazepine.
- Medicines containing Iodine such as: Potassium Iodide.
- Calcium channel blockers such as: Diltiazem, Nifedipine, Verapamil.
- Neuromuscular Blocking medicines such as: Succinylcholine, Pancuronium.

Do not start or stop taking other medicines during treatment with this medicine without first consulting the doctor.

#### **Use of this medicine and food**

Swallow the medicine with/ after food or milk, in order to prevent diarrhea and gastrointestinal disorders.

#### **Pregnancy and breastfeeding:**

- Tell your doctor before starting treatment if you are pregnant or plan to become pregnant. The medicine may harm the fetus.
- Tell your doctor before starting treatment if you are breastfeeding or planning to breastfeed. Lithium Carbonate can pass into breast milk and may harm the baby. Do not breastfeed during treatment with the medicine. Discuss with your doctor the best way to feed your baby if you are taking this medicine.
- If you have been exposed to this medicine during pregnancy, especially during the first trimester, you must consult with one of the teratology consultation centres, in order to evaluate the risk of harm to the fetus.

#### **Driving and using machines:**

At the beginning of treatment with the medicine or when the dose changes, do not drive, operate dangerous machinery or perform any other dangerous activities until you know how the medicine affects you. The medicine may cause drowsiness. Discuss these activities with your doctor.

#### **Important information about some of the ingredients of the medicine**

**Licarbium** contains less than 1 millimole of sodium (23 mg) per tablet, that is to say essentially "sodium free".

### **3. How to use this medicine?**

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.

The dosage and manner of treatment will be determined by the doctor only. Your doctor may alter the dose of the medicine, in order to ensure that you are taking the appropriate dose for you. Do not alter the dose on your own.

#### **Do not exceed the recommended dose.**

#### **Method of administration:**

- Swallow the medicine with/ after food or milk, in order to prevent diarrhea and gastrointestinal disorders.
- For ease of swallowing, if necessary, the tablet may be halved /crushed for immediate use. No information is available about the uniformity of split halves.

#### **If you have accidentally taken a higher dosage**

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

#### **If you forgot to take the medicine**

If you forgot to take the medicine at the designated time, consult the doctor. If you forgot to take the medicine, do not take a double dose. Take a dose as soon as you remember. Skip the dose only if two hours remain before the next dose.

#### **If you stop taking the medicine**

Adhere to the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Improvement in the condition will occur only 1-3 weeks from the beginning of the treatment.

**Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them. If you have further questions on the use of this medicine, consult the doctor or pharmacist.**

### **4. Side effects**

Like any medicine, the use of **Licarbium** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

#### **Severe side effects:**

**Stop taking this medicine and refer to the doctor immediately if you suffer from any symptoms of Lithium toxicity (excessive blood lithium content which may lead to death and which may occur even when blood lithium levels are close to the levels you require), including:**

- Abnormal heartbeat
  - Muscle weakness
  - Muscle twitching
  - Vomiting
  - Diarrhea
  - Blurred vision
  - Drowsiness
  - Ringing in your ears (tinnitus)
  - Clumsy movements
- Other symptoms may include:
- Confusion
  - Lightheadedness
  - Mood changes
  - Breathing problems
  - Seizure
  - Slurred speech
  - Bloated stomach
  - Coma

#### **Refer to the doctor immediately if you suffer from any of the following severe side effects:**

- **Kidney problems:** People who take this medicine may suffer from urinary frequency (polyuria) and other kidney problems, which may affect kidney function. These problems may occur within several weeks after starting to take Lithium Carbonate or after taking the medicine for a long period of time.
- **Low levels of sodium (salt) in your blood (hyponatremia):** The medicine may cause you to lose sodium. When starting treatment with the medicine, have a discussion with your doctor about your diet and fluid intake. If you have been sweating more than usual or have had diarrhea, you may need extra salt and more fluids. Talk to your doctor if this happens.

- **Neurological problems:** People who take this medicine along with certain other medicines called antipsychotics, may suffer from symptoms such as: weakness, tiredness, fever, tremors and confusion. Ask the doctor if you are unsure about the medications you are taking.
- **Serotonin syndrome:** A potentially life-threatening phenomenon called Serotonin syndrome, which may occur when Lithium Carbonate is taken together with certain medicines called Monoamine oxidase inhibitors (MAOIs) and medicines affecting serotonin levels (Serotonergic). Symptoms of Serotonin syndrome include: agitation, coma, dizziness, fever, muscle twitching, nausea, vomiting, seeing things that are not there, rapid pulse, sweating, tremors, become unstable, confusion, high or low blood pressure, flushing, stiff muscles, seizures, diarrhea.
- **Thyroid gland problems.**
- **High blood calcium levels (hypercalcemia) and changes in the parathyroid gland (hyperparathyroidism),** which may persist after discontinuation of the medicine.
- **Heart problems:** People who take this medicine may discover that they also suffer from a heart condition called Brugada syndrome. People who have unexplained fainting or have a family history of sudden unexplained death before 45 years of age, may have Brugada syndrome and not know it. Talk to your doctor if you faint or feel abnormal heartbeats right away.
- **Increased pressure in the brain and swelling in the eyes (Pseudotumor cerebri)** that can cause vision problems or blindness. Severe headaches behind the eyes, ringing in the ears (tinnitus), blurred vision, double vision or brief periods of blindness.

The most common side effects:

In adults:

Hand trembling, urinary frequency, increased thirst, nausea, a feeling of general discomfort at the start of treatment.

In children aged 12-17:

Urinary frequency, thyroid gland problems, hand trembling, excessive thirst, dizziness, rash, difficulty walking, loss of appetite, blurred vision, nausea, vomiting.

**If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.**

**Report of side effects**

Side effects can be reported to the Ministry of Health by clicking on the link "Report adverse effects and problems associated with medications and drugs" on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)), which links to an online form for reporting side effects, or by following the link: <https://sideeffects.health.gov.il>

**5. How to store the medicine?**

- Avoid poisoning! This medicine and any other medicine must be stored in a close place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store in a dry place below 25°C.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Additional information**

**In addition to the active ingredient, this medicine also contains:**

Starch, Talc, Magnesium Stearate, Croscarmellose Sodium (Ac-Di-Sol), Colloidal Silicon Dioxide (Aeosil 200), Sodium Carboxymethylcellulose (C.M.C. Sodium 7MF).

**What the medicine looks like and what the package contains:**

A white round, flat beveled edges tablets, "REKAH" engraved on one side and plain on the other.

Approved package size: 100 tablets.

**Manufacturer and registration holder:**

Rekah Pharmaceutical Industries Ltd., 30 Hamelacha St. Holon, Israel.

Revised in July 2022 according to Ministry of Health guidelines.

**Drug registration number at the national drug registry of the Ministry of Health:** 022-10-20683-00