

Package Leaflet: Information for the User

Liskonum[®] 450 mg tablets
lithium carbonate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1 What Liskonum is and what it is used for
- 2 What you need to know before you take Liskonum
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1 What Liskonum is and what it is used for

Liskonum tablets contain the active substance lithium carbonate.

Liskonum is used in adults and children over 12 years of age to:

- **prevent** you feeling overactive, overly elated (happy) or overly irritable
- **stop** big changes in your mood. You may go from feeling very sad and unworthy to feeling overactive, overly elated (happy) or overly irritable. In some people the change can be reversed.

Liskonum tablets are 'controlled release' tablets. This means the lithium carbonate is slowly released into your body, which stops large changes in the levels of lithium in your blood.

2 What you need to know before you take Liskonum

Do not take Liskonum if:

- you are **allergic (hypersensitive) to lithium** or any of the other ingredients of this medicine (listed in section 6)
- you have **kidney or heart problems**
- you have **thyroid problems** that are not being treated. Signs of thyroid problems include: tiredness, lethargy, muscle weakness, cramps, feeling cold, a slow heart rate, dry and flaky skin, hair loss, a deep and husky voice and weight gain
- **you are dehydrated, such as when you are being sick (vomiting) or have diarrhoea**
- **you are on a low sodium diet**
- **you have Addison's Disease.** This is when your adrenal glands are not working properly which may cause weakness, tiredness, weight loss and low blood pressure

- you or someone in your family has a condition called **Brugada syndrome** (a hereditary disease that affects the heart).

Do not take if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Liskonum.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Liskonum if:

- you have an **infection**
- you have an **intolerance to some sugars**. Each Liskonum 450 mg tablet contains 62 mg lactose per dose. This should be taken into account in patients with sugar diabetes (diabetes mellitus)
- you have **kidney impairment**. Patients with severe kidney impairment who received lithium for more than 10 years may have a risk of developing a benign or malignant kidney tumour (microcysts, oncocytoma or collecting duct renal carcinoma)
- you have a family history of cardiac arrest or sudden death.
- you have a condition called Brugada syndrome (a hereditary syndrome that affects the heart), or if anyone in your family has had Brugada syndrome, heart arrest or sudden death.
- You are planning, or have already had weight loss surgery, as a lower dose of lithium may be required. Your doctor will monitor the level of lithium in your blood and adjust your dose accordingly.

Children under the age of 12 years:

This medicine is not recommended for use in children under 12 years of age.

Other medicines and Liskonum

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because Liskonum can affect the way some other medicines work. Also some other medicines can affect the way Liskonum works.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- **diuretics (water tablets)** - used to increase the amount of urine produced (such as furosemide and bendroflumethiazide)
- **non-steroidal anti-inflammatory medicines (NSAIDs)**, including Cox-II inhibitors - used for pain and rheumatism (such as ibuprofen, diclofenac, celecoxib and etoricoxib)
- **selective serotonin re-uptake inhibitors (SSRIs)** - used for depression (such as fluvoxamine and fluoxetine)
- **neuroleptic medicines** - used for nervous disorders like schizophrenia (such as haloperidol)
- **medicines for epilepsy** (such as carbamazepine)
- **metronidazole** - used to treat infections
- **medicines used to relax muscles during surgery**
- **medicines used to treat high blood pressure and some other heart problems** (such as methyl dopa, ACE inhibitors, calcium channel blockers and angiotensin II antagonists)
- **medicines containing sodium bicarbonate** - used to treat heartburn and indigestion (such as antacids)
- **urea** - used to treat skin conditions
- **xanthines** - used in the treatment of asthma (such as theophylline and aminophylline)
- **empagliflozin** – used to treat diabetes or heart failure
- **dapagliflozin** – used to treat diabetes or heart failure or chronic kidney disease.

- **Topiramate** – used to treat epilepsy or migraine

Electric shock treatment (*electroconvulsive therapy* or ECT)

- Because of the increased risk of side effects such as severe confusion (delirium) and fits that may last longer than usual (prolonged seizures), your doctor may take a blood sample to check the level of Lithium in your blood before receiving electric shock treatment.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Liskonum.

Pregnancy and breast-feeding

Do not take Liskonum if you are pregnant, might become pregnant or breast-feeding, unless your doctor tells you to. Talk to your doctor before taking this medicine if you are not sure.

Driving and using machines

You may feel drowsy, dizzy or see, feel or hear things that are not there (hallucinations) while taking Liskonum. If this happens, do not drive or use any tools or machines.

Liskonum contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3 How to take Liskonum

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Your doctor will tell you how much Liskonum to take and how often. This depends on your condition. It is usually taken twice a day.
- Your doctor will do blood tests to check the amount of lithium in your blood.
- Swallow the tablets with a glass of water.
- Do not crush or chew the tablets. If you struggle to swallow the tablets they can be broken in half, but you must try to swallow each half, do not chew it.
- You should try to take your medicine at the same time each day.
- If you feel the effect of your medicine is too weak or too strong do not change the dose yourself, talk to your doctor.
- Do not stop taking Liskonum suddenly as this **may worsen** your underlying symptoms. If your doctor feels that your treatment should be stopped, then your dose **should** usually be gradually reduced rather than immediately stopped.
- Do not take more Liskonum than your doctor has recommended.

Thoughts of harming or killing yourself

If you have a mood disorder, you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting Liskonum or changing your dose of Liskonum. Like other medicines of this kind, Liskonum may not relieve your symptoms straight away. If you have thoughts of harming or killing yourself or worsening of your symptoms at any time, **contact your doctor or go to a hospital straight away.**

You may find it helpful to tell a relative, close friend or carer that you have a mood disorder, and ask them to read this leaflet. You might ask them to tell you if they think your mood disorder is getting worse, or if they are worried about changes in your behaviour.

Use in children

Liskonum is not suitable for children under 12 years of age.

Use in the elderly (over 65 years)

Older people may need to start on a lower dose.

Salt and water intake while taking Liskonum

Your salt and water intake affects the way that lithium is removed from your body. **This means you need to maintain a sufficient and steady supply of both salt and water.**

Drink about the same amount of **water** every day (the usual range is 4-6 pints) and avoid any dramatic changes in your fluid intake.

- If you usually drink less than 4-6 pints of fluid each day, and blood tests show that your lithium level is stable, there is no need to drink more water.
- However, do not ignore any feelings of thirst. Have a drink when you feel you need to.

Keep to your normal, daily amount of **salt**.

- Tell your doctor before you begin any new diets. Do not start a low sodium diet while taking Liskonum.
- Do not fast while taking Liskonum.

If you take more Liskonum than you should

If you take more Liskonum than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Liskonum

- If you forget a dose, miss out that dose completely.
- Take your next dose at the usual time.
- Do not take a double dose (two doses at once) to make up for a forgotten dose.

If you stop taking Liskonum

- Take Liskonum for as long as your doctor recommends. Do not stop suddenly as your illness may get worse. If you need to stop taking it, your doctor will usually reduce your dose gradually.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor straight away and stop taking Liskonum if you notice any of the following side effects:

- being sick (vomiting) or diarrhoea
- lack of co-ordination (clumsiness), increased shaking of your hands and lower jaw, muscle twitching or jerking movements, numbness and weakness of the arms and legs, fingers and toes, loss of sensation and pins and needles, joint pain or muscle pain
- dizziness, blurred vision or worsening of eyesight
- ringing in your ears.

Do not take any further doses of your medicine unless your doctor advises you to do so. The amount of Liskonum in your blood may be too high and you may need to stop taking this medicine.

The following side effects may also happen with this medicine:

Heart and circulation

- water retention and swelling (oedema)
- changes in your heart rate, most commonly a slow heartbeat, or a drop in blood pressure (hypotension)
- blood tests can show an increase in white blood cells (leukocytosis), increased blood sugar (hyperglycaemia) or increased calcium levels.
- Frequency not known: Unmasking and/or aggravation of Brugada Syndrome (a hereditary syndrome that affects the heart)

Nervous system

- slurred speech or feeling dazed
- spinning sensation (vertigo)
- sleepiness, memory loss or hallucinations (sensing things that are not real)
- mild shaking of your hands or jerky muscle movements when you first start to take Liskonum
- seizures, fits or convulsions, decreased or loss of consciousness (coma)
- headache.

Skin and hair

- acne, swelling and redness (inflammation) around hair follicles and rashes, which can be itchy or raised (papular) can occur. If you suffer from psoriasis, this may get worse
- unusual hair loss or thinning can also occur
- numbness, tingling and colour changes (white, blue then red) in your fingers and toes when they are cold.
- frequency not known: eruption of the skin or mucous membranes (lichenoid drug reaction)
- frequency not known: widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involment (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome). Stop using Liskonum if you develop these symptoms and contact your doctor or seek medical attention immediately.

Stomach and gut

- feeling sick (nausea)
- inflamed stomach (gastritis) which may cause pain, vomiting blood or blood in your bowel motions
- taste disturbance
- loss of appetite or weight gain.

Thyroid

- lower (hypothyroidism) or, rarely, higher activity (hyperthyroidism) of your thyroid gland can occur. Hypothyroidism may make you feel very tired and slow. Hyperthyroidism may increase your appetite, result in loss of weight, intolerance to heat, increased sweating and tremors
- increases in the activity of your parathyroid gland (hyperparathyroidism) can also occur and can cause tiredness, vomiting, bone pain or tenderness, and produce too much parathyroid hormone, which raises calcium levels in the blood.
- increase in the size of your thyroid gland with normal thyroid activity (euthyroid goitre).
- Increased size of the parathyroid glands.
- Parathyroid adenoma (a non-cancerous tumour).

Others

- kidney problems. Frequency unknown of benign/malignant kidney tumours (microcysts,

- oncocytoma, or collecting duct renal carcinoma) in long-term therapy.
- muscle weakness, giddiness
- rapid, uncontrollable eye movements
- you may feel thirsty while taking Liskonum and need to drink more liquids (see advice under Salt and water intake while taking Liskonum in section 3)
- you may need to pass water (urinate) more often
- you may have a dry mouth, or find you are producing more saliva than normal
- sexual dysfunction.
- Frequency very frequent: too much calcium in your blood.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Liskonum

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the foil and carton. The expiry date refers to the last day of that month.
- Do not store Liskonum tablets above 25°C.
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Liskonum contains

- The active substance is lithium (present as lithium carbonate) 450 mg
- The other ingredients are povidone, maize starch, lactose (see section 2), gelatin, calcium carboxymethylcellulose, talc (E553[b]), calcium arachinate, titanium dioxide (E171), magnesium stearate (E572), polyethylene glycol 6000, eudragit E12.5

What Liskonum looks like and contents of the pack

Liskonum tablets are white, oblong, film-coated tablets, with a score (breakline) on both sides. Liskonum tablets come in packs of 60 tablets, arranged in three blister strips of 20 tablets.

Marketing authorisation holder and manufacturer

Marketing Authorisation Holder:

Teofarma S.r.l. Via F.lli Cervi, 8 – 27010 Valle Salimbene (PV) – Italy

Manufacturer: Teofarma S.r.l. Viale Certosa, 8/A – 27100 Pavia - Italy

Hard to read? Send an e-mail to servizioclienti@teofarma.it for help.

This leaflet was last revised in July 2024