

Lamotrigine Cas No. : 84057-84-1

Lamotrigine is used alone or with other medications to prevent or control seizures (epilepsy) in people aged 2 and older. It may also be used to help prevent the extreme mood swings of bipolar disorder in people aged 18 and older.

Active Pharmaceuticals Ingredients Manufacturers



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Taj Pharmaceuticals Ltd.**Lamotrigine****CAS No. : 84057-84-1****Systematic (IUPAC) name**

6-(2,3-dichlorophenyl)-1,2,4-triazine-3,5-diamine

Molecular Formula C₉H₇Cl₂N₅

Molecular Weight 256.09

CAS Registry Number 84057-84-1

EINECS 281-901-8

Identifiers

CAS number 84057-84-1

ATC code N03AX09

PubChem 3878

DrugBank APRD00570

ChemSpider 3741

Chemical data

Formula C₉H₇Cl₂N₅

Mol. mass 256.091 g/mol

SMILES eMolecules & PubChem

Pharmacokinetic data

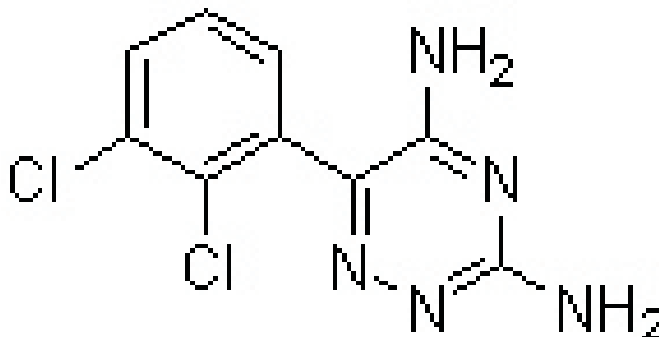
Bioavailability 98%

Protein binding 55%

Metabolism Hepatic (mostly UGT1A4-mediated)

Half life 24–34 hours (healthy adults)

Excretion Renal



Lamotrigine is used alone or with other medications to prevent or control seizures (epilepsy) in people aged 2 and older. It may also be used to help prevent the extreme mood swings of bipolar disorder in people aged 18 and older.

This medication is an anticonvulsant. Lamotrigine is thought to work by restoring the balance of certain natural substances (neurotransmitters) in the brain.

HOW TO USE

Take this medication with or without food as directed by your doctor. Lamotrigine tablets should be swallowed whole. Chewing the tablets may leave a bitter taste. **SIDE EFFECTS:** Dizziness, headache, blurred/double vision, nasal congestion, lack of coordination, shaking (tremor), muscle weakness, drowsiness, nausea, vomiting, diarrhea, painful menstrual cramps, difficulty sleeping, and lower stomach/abdominal discomfort may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. **PRECAUTIONS:** Before taking lamotrigine, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies.

MISSED DOSE

It is important to take each dose at the scheduled time. If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.



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Lamotrigine

CAS NO- 84057-84-1

STORAGE

Store at room temperature at 77 degrees F (25 degrees C) away from heat, light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom. Keep all medicines away from children and pets.

SIDE EFFECTS

Lamotrigine may cause side effects

- * loss of balance or coordination
- * double vision
- * blurred vision
- * crossed eyes
- * difficulty thinking or concentrating
- * difficulty speaking
- * drowsiness
- * dizziness
- * vomiting
- * diarrhea
- * constipation
- * heartburn
- * problems with ears or teeth
- * irritability
- * nervousness
- * mood changes
- * difficulty falling asleep or staying asleep
- * stomach, back, or joint pain
- * runny nose
- * cough
- * missed or painful menstrual periods}
- * swelling, itching, or irritation of the vagina
- * dry mouth



Some side effects can be serious. If you experience any of the following symptoms or those described in the IMPORTANT WARNING section, call your doctor immediately:

- * seizures that happen more often, last longer, or are different than the seizures you had in the past
- * chest pain
- * swelling of the hands, feet, ankles, or lower legs
- * depression

DOSAGE

Lamotrigine comes as a regular tablet and a chewable dispersible (can be chewed or dissolved in liquid) tablet to take by mouth. It is usually taken once or twice a day. It is sometimes taken once every other day at the beginning of treatment. Follow the directions on your prescription label carefully and ask your doctor or pharmacist to explain any part you do not understand.

There are other medications that have names similar to the brand name for lamotrigine. You should be sure that you receive lamotrigine and not one of the similar medications each time you fill your prescription. Swallow the regular tablets whole; do not split, chew, or crush them.



If you are taking the chewable dispersible tablets, you may swallow them whole, chew them, or dissolve them in liquid. If you chew the tablets, drink a small amount of water or diluted fruit juice afterward to wash down the medication. To dissolve the tablets in liquid, place 1 teaspoon of water or diluted fruit juice in a glass or on a spoon. Place the tablet in the liquid and wait 1 minute to allow it to dissolve. Then mix the liquid and drink all of it immediately.

If you were taking another medication to treat seizures and are switching to lamotrigine, your doctor will gradually decrease your dose of the other medication and gradually increase your dose of lamotrigine. Follow these directions carefully and ask your doctor or pharmacist if you have questions about how much of each medication you should take. Lamotrigine may control your condition, but it will not cure it. Continue to take lamotrigine even if you feel well. Do not stop taking lamotrigine without talking to your doctor. Your doctor will probably decrease your dose gradually. If you suddenly stop taking lamotrigine, you may experience seizures. If you do stop taking lamotrigine for any reason, do not start taking it again without talking to your doctor.

DRUG DESCRIPTION

Lamotrigine is a novel anticonvulsant drug which has multiple mechanisms of action. Along with epilepsy, it has become the treatment of choice in many areas of medicine, including various psychiatric disorders and pain syndromes. In psychiatry, there are several studies reporting the efficacy of lamotrigine in the treatment of bipolar disorder, schizophrenia, cocaine dependence, post traumatic stress disorder and borderline personality disorder. In these studies, lamotrigine was seen to be well tolerated, to be an effective mood stabilizer, to be significantly more effective in schizophrenia when given as adjunctive therapy to clozapine. However it requires medical attention when combined with other antipsychotics except for clozapine due to possible iatrogenic worsening of psychiatric symptoms. Lamotrigine has been reported to have positive treatment effects for other potential clinical applications in limited number of reports. The literature related with lamotrigine use for the treatment of different psychiatric disorders

Chewable Dispersible Tablets are supplied for oral administration. The tablets contain 2 mg (white), 5 mg (white), or 25 mg (white) of lamotrigine and the following inactive ingredients: blackcurrant flavor, calcium carbonate, low-substituted hydroxypropylcellulose, magnesium aluminum silicate, magnesium stearate, povidone, saccharin sodium, and sodium starch glycolate.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:
91 022 30601000.

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