Gabapentin Cas No.: 60142-96-3

This section contains uses of this drug that are not listed in the approved professional labeling for the drug but that may be prescribed by your health care professional. Use this drug for a condition that is listed in this section only if it has been so prescribed by your health care professional.

Active Pharmaceuticals Ingredients Manufacturers



Taj Pharmaceuticals Ltd. Gabapentin CAS No.: 60142-96-3

Molecular Weight 207.70

Systematic (IUPAC) name

2-[1-(aminomethyl)cyclohexyl]acetic acid

Identifiers

CAS number 60142-96-3 ATC code N03AX12 PubChem 3446 DrugBank APRD00015

Chemical data

Formula C9H17NO2 Mol. mass 171.237 g/mol

Pharmacokinetic data

Bioavailability Rapid, in part by saturable carrier-mediated L-amino acid transport system 60% for 0.9 g daily to 27% for 4.8 g daily dose Food increases absorption by 14% Protein binding Less than 3% Metabolism Not appreciably metabolized Half life 5 to 7 hours **Excretion Renal**

DOSAGE

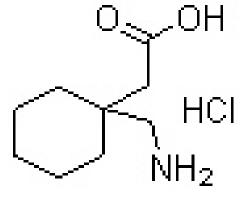
Gabapentin may be taken with or without food. The recommended dose for postherpetic neuralgia is 1800 mg daily in 3 divided doses. The initial dose of 300 mg daily is increased over several days to the recommended daily dose. Seizures are treated with 900-1800 mg/daily in 3 divided doses. Withdrawal of treatment should occur slowly over a week.

Take this medication by mouth, with or without food, as directed by your doctor. The dosage is based on your medical condition and response to therapy. During the first few days, your doctor may gradually increase your dose so your body can adjust to the medication. To minimize side effects, take the very first dose at bedtime. Use this medication regularly in order to get the most benefit from it. This drug works best when the amount of medicine in your body is kept at a constant level. Therefore it is best to take gabapentin at evenly spaced intervals throughout the day and night. Do not take this medication more often or increase your dose without consulting your doctor. Your condition will not improve any faster and the risk of serious side effects may be increased. Do not stop taking this medication without consulting your doctor. Some conditions such as seizures may become worse when the drug is abruptly stopped. Your dose may need to be gradually decreased. Antacids containing aluminum or magnesium may interfere with the absorption of this medication. Therefore it is best to take gabapentin at least 2 hours after taking an antacid.



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For adults, the initial dose of gabapentin is 300 mg taken by mouth three times each day. The dosage may be increased if necessary. Dosages as high as 800–1,200 mg three times daily have been well tolerated.

In children three to 12 years of age, the starting dose should be 10–15 mg/2.2 lb (1 kg)/day given in three equal doses. This dose can be increased until an effective dosage is reached, typically 25–40 mg/2.2 lb (1 kg)/day. Lower dosages are required for patients that have kidney disease.

SIDE EFFECTS

Drowsiness, dizziness, unsteadiness, fatigue, vision changes, weight gain, nausea, dry mouth, or constipation may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Tell your doctor immediately if any of these serious side effects occur: tremor or shaking, swollen arms/legs. Tell your doctor immediately if any of these unlikely but serious side effects occur: loss of coordination, mental/mood changes. Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: persistent sore throat/fever/cough, unusual bleeding/bruising, pain/redness of arms or legs, chest pain, trouble breathing, fast/slow/irregular heartbeat, hearing loss, stomach/abdominal pain. If you notice other effects not listed above, contact your doctor.

The most common side effects that cause adults to stop taking gabapentin are dizziness, sleepiness, fatigue, shaky movements, difficulty walking, or swelling in the ankles.

In children, the side effects the drug may cause include emotional problems, hostility, and hyperactivity.

PRECAUTIONS

In children, gabapentin may cause behavioral and emotional disorders. The drug should be used cautiously and the dosage should be reduced in those with severe kidney disease. In experimental animals, gabapentin caused tumors to develop; however, it is not known if this occurs in humans.

Patients should take gabapentin only as prescribed. The drug should never be stopped abruptly because doing so increases the likelihood of having a seizure. Since gabapentin can cause dizziness and fatigue, patients should avoid driving or operating complex machinery until they know whether the drug adversely affects their reaction time or impairs their judgment.

Gabapentin should not be discontinued abruptly after long term use. Abrupt or over rapid withdrawal may provoke a withdrawal syndrome similar to alcohol or benzodiazepine withdrawal. Gradual reduction over a period of weeks or months helps minimise or prevents the withdrawal syndrome

Before taking gabapentin, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney disease. This drug may make you dizzy or drowsy; use caution engaging in activities requiring alertness such as driving or using machinery. Limit alcoholic beverages as they may worsen these effects. Caution is advised when using this drug in the elderly because they may be more sensitive to its effects, especially swollen arms/legs or loss of coordination. Caution is advised when using this drug in children because they may be more sensitive to its effects, especially the mental/mood changes (e.g., hostility). This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. Gabapentin passes into breast milk. Because the effects of this drug on the nursing infant are unknown, consult your doctor before breast-feeding.



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DRUG DESCRIPTION

Gabapentin is a GABA analogue. It was originally developed for the treatment of epilepsy, and currently, gabapentin is widely used to relieve pain, especially neuropathic pain.

Gabapentin is an anticonvulsant that is used for preventing seizures and for treating postherpetic neuralgia. The mechanism of action of gabapentin is not known. Gabapentin structurally resembles the neurotransmitter gamma aminobutyric acid (GABA). It is possible that this similarity is related to gabapentin's mechanism of action. In animal models used for testing the anticonvulsant and analgesic activity of drugs, gabapentin prevents seizures and reduces pain-related responses

Gabapentin is an anticonvulsant that is chemically unrelated to any other anticonvulsant or mood regulating medication.



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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. This leaflet was prepared by Taj Pharmaceuticals Limited, Mumbai (India). MPSTJ278 Last revised: 29 August 2009

