

Zolmitriptan Cas No. : 139264-17-8

Zolmitriptan is used to treat migraines. It helps to relieve headaches, pain, and other symptoms of migraines, including nausea, vomiting, and sensitivity to light/sound. Prompt treatment allows you to get back to your normal routine and may decrease your need for other pain medications. Zolmitriptan does not prevent future migraines or reduce how often you may get a migraine.

Active Pharmaceuticals Ingredients Manufacturers



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Taj Pharmaceuticals Ltd.**Zolmitriptan****CAS No. : 139264-17-8****Synonyms: (IUPAC) name**

(4S)-4-({3-[2-(dimethylamino)ethyl]-1H-indol-5-yl}methyl)-1,3-oxazolidin-2-one

Identifiers

CAS number 139264-17-8

ATC code N02CC03

PubChem 60857

DrugBank APRD00376

Chemical dataFormula C₁₆H₂₁N₃O₂

Mol. mass 287.357 g/mol

Pharmacokinetic data

Bioavailability 40% (oral)

Protein binding 25%

Metabolism

Half life 3 hours

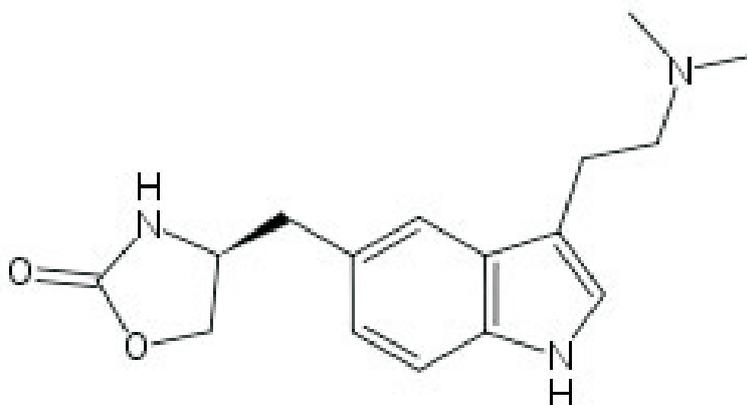
Excretion Renal (65%) and fecal (35%)

Therapeutic considerations

Pregnancy cat.

B3(AU) C(US)

Routes Oral, nasal spray



Zolmitriptan is a selective 5-hydroxytryptamine 1B/1D (5-HT_{1B/1D}) receptor agonist. Zolmitriptan is chemically designated as (S)-4-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-2-oxazolidinone.

The empirical formula is C₁₆H₂₁N₃O₂, representing a molecular weight of 287.36. Zolmitriptan is a white to almost white powder that is readily soluble in water. ZOMIG Tablets are available as 2.5 mg (yellow) and 5 mg (pink) film coated tablets for oral administration.

The film coated tablets contain anhydrous lactose NF, microcrystalline cellulose NF, sodium starch glycolate NF, magnesium stearate NF, hydroxypropyl methyl-cellulose USP, titanium dioxide USP, polyethylene glycol 400 NF, yellow iron oxide NF (2.5 mg tablet), red iron oxide NF (5 mg tablet), and polyethylene glycol 8000 NF.

USES

Zolmitriptan is used to treat migraines. It helps to relieve headaches, pain, and other symptoms of migraines, including nausea, vomiting, and sensitivity to light/sound. Prompt treatment allows you to get back to your normal routine and may decrease your need for other pain medications. Zolmitriptan does not prevent future migraines or reduce how often you may get a migraine.

Zolmitriptan belongs to a group of drugs called "triptans." Migraines are thought to occur when certain blood vessels in the brain become swollen (dilated). This drug works by helping blood vessels in the brain to return to normal size. It may also block pain signals in the brain.



Taj Pharmaceuticals Ltd.
Zolmitriptan

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HOW TO USE

Read the Patient Information Leaflet available. Your dosage is based on your medical condition and response to treatment.

Take this medication by mouth, with or without food, at the first sign of a migraine as directed by your doctor. If there is no improvement in your symptoms, do not take any more doses of this medication before talking to your doctor. If your symptoms are only partly relieved, or if your headache comes back, you may take a second dose after 2 hours or as directed by your doctor. Do not take more than 10 milligrams in a 24-hour period.

SIDE EFFECTS

Tingling/numbness, nausea, dry mouth, weakness, drowsiness, or dizziness may occur. If any of these effects persist or worsen, tell your doctor

Tell your doctor immediately if any of these unlikely but serious side effects occur: blue fingers/toes/nails, cold feeling in the hands/feet.

Pain/pressure/tightness in the chest/neck/jaw can occur shortly after using zolmitriptan. These side effects are usually not serious. However, you may not be able to tell them apart from a rare but very serious reaction related to a lack of blood flow to the heart, brain, or other parts of the body. Therefore, seek immediate medical attention if you notice any of these unlikely side effects: chest/jaw/left arm pain, fainting, irregular/pounding heartbeat, vision changes, severe nausea, weakness on one side of the body, confusion, seizures, slurred speech, sudden or severe stomach/abdominal pain, trouble swallowing, bloody diarrhea.

This medication may rarely cause a very serious condition called serotonin syndrome. The risk increases when this medication is used with certain other drugs such as other "triptans" used to treat migraine headaches (e.g., sumatriptan, eletriptan), certain antidepressants including SSRIs (e.g., citalopram, fluoxetine, paroxetine) and NSRIs (e.g., duloxetine, venlafaxine), or a certain drug to treat obesity (sibutramine). Before taking this drug, tell your doctor if you take any of these medications. Serotonin syndrome may be more likely when you start or increase the dose of any of these medications. Seek immediate medical attention if you develop some of the following symptoms: hallucinations, unusual restlessness, loss of coordination, fast heartbeat, severe dizziness, high fever, severe nausea/vomiting/diarrhea, twitchy muscles. A very serious allergic reaction to this drug is rare

PRECAUTIONS

This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: heart disease (e.g., chest pain, heart attack, irregular heartbeat, coronary artery disease, vasospasm), blood flow problems in the brain (e.g., stroke, transient ischemic attack), blood vessel disease (e.g., peripheral vascular disease, ischemic bowel disease), uncontrolled high blood pressure (hypertension), certain types of headaches (hemiplegic or basilar migraine), severe liver disease.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: blood circulation disorder (e.g., Raynaud's disease), kidney disease.

Before using this medication, tell your doctor or pharmacist if you have any condition that increases your risk of heart disease, including: high cholesterol level, high blood pressure, diabetes, smoking history, family history of heart disease or stroke, overweight, female after menopause, male older than 40 years.

MISSED DOSE

Not applicable.



STORAGE

Store the US product at room temperature between 68-77 degrees F (20-25 degrees C) away from light and moisture. Store the Canadian product at room temperature between 59-86 degrees F (15-30 degrees C) away from light and moisture.

Do not store in the bathroom. Keep all medicines away from children.

DOSAGE

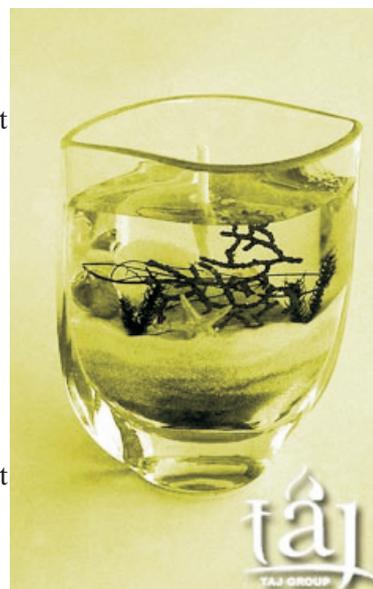
Take this drug by mouth as directed. If relief occurs after one dose, but the headache returns, the dose may be repeated after 2 hours if so directed by your doctor. If you have no relief with the first dose, do not take a second dose without consulting your doctor. Do not take more than 10mg in a 24 hour period.

Read the Information Leaflet available from your pharmacist. If you have never taken this medication before and you have risk factors for heart disease (see Precautions), you may be advised to take the very first dose in your doctor's office in order to monitor for rare but serious heart problems.

Zolmitriptan comes as a tablet and an orally disintegrating tablet (tablet that dissolves quickly in the mouth) to take by mouth. It is usually taken during a migraine attack.

If your symptoms improve after you take zolmitriptan but return after 2 hours or longer, you may take a second dose. However, if your symptoms do not improve after you take zolmitriptan, do not take a second dose without calling your doctor.

Your doctor will tell you the maximum number of tablets or orally disintegrating tablets you may take in a 24-hour period. Call your doctor if you need to take zolmitriptan to treat more than three headaches in 1 month. Follow the directions on your prescription label carefully, and ask your doctor to explain any part you do not understand.



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.

This leaflet was prepared by
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