Naratriptan Cas No.: 121679-13-8

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

Active Pharmaceuticals Ingredients Manufacturers





Systematic (IUPAC) name

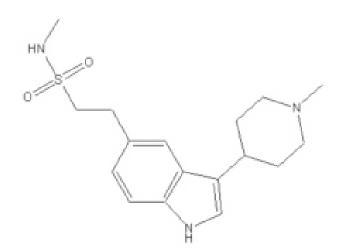
N-methyl-2-[3-(1-methylpiperidin-4-yl)-1H-indol-5-yl]ethanesulfonamide

Identifiers

CAS number 121679-13-8 ATC code N02CC02 PubChem 4440 DrugBank APRD00220

Chemical data

Formula C17H25N3O2S Mol. mass 335.465 g/mol Pharmacokinetic data Bioavailability 74% Metabolism Hepatic Half life 5-8 hours Excretion Renal



Naratriptan used for the treatment of migraine headaches. Naratriptan is available in 2.5 mg tablets. It is a selective 5-hydroxytryptamine1 receptor subtype agonist. Naratriptan hydrochloride is chemically designated as N-methyl-3-(1-methyl-4-piperidinyl)-1H-indole-5-ethanesulfonamide.

Uses

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

Naratriptan belongs to a group of drugs called triptans. It affects a certain natural chemical (serotonin) that constricts blood vessels in the brain. It may also block other pain pathways in the brain.

How to use

Take one tablet by mouth with or without food, at the first sign of a migraine, or as directed by your doctor. Do not take naratriptan to prevent a migraine. 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 4 hours or as directed by your doctor. Do not take more than 5 milligrams in a 24-hour period.

If you have never taken this medication before and you have risk factors for heart disease (see Precautions), you may be advised to take your first dose in your doctor's office in order to monitor for rare but serious heart problems (e.g., heart attack).





Taj Pharmaceuticals Ltd.

Naratriptan

CAS No 121679-13-8

Side Effects

This medication may rarely cause a very serious condition called serotonin syndrome. The risk increases when this medication is taken with certain other drugs such as other "triptans" used to treat migraine headaches (e.g., sumatriptan, zolmitriptan), 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.

Precautions

This medication should not be taken if you have certain medical conditions. Before using this medication, consult your doctor or pharmacist if you have a history of: heart disease (e.g., chest pain, heart attack), decreased blood flow in the brain (e.g., stroke, transient ischemic attack), blood circulation disease (e.g., ischemic bowel disease), uncontrolled high blood pressure (hypertension), certain types of headaches (hemiplegic or basilar migraine), kidney disease, liver disease.

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

Tell your doctor if you have the following risk factors for heart disease: diabetes, family history of heart disease, high blood pressure (controlled), high cholesterol, overweight, smoker, female after menopause, male over age 40

If you are at high risk for heart disease, your doctor may want to check your heart before prescribing naratriptan.

This drug may make you dizzy or drowsy; use caution engaging in activities requiring alertness such as driving or using machinery. Limit alcoholic beverages.

The risk of heart disease, liver disease, and high blood pressure increases with age. The manufacturer does not recommend the use of naratriptan in the elderly since they may be more sensitive to the side effects, especially to an increase in blood pressure.

MISSED DOSE

Not applicable.

STORAGE

Store the US product at room temperature between 68 and 77 degrees F (20-25 degrees C) away from light and moisture. Store the Canadian product below 86 degrees F (30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.

DOSAGE

Naratriptan comes as a tablet to take by mouth. It should be taken at any time after a migraine headache starts. Usually only one tablet is needed. If you have no response to the first tablet, do not take a second tablet without consulting your doctor. If you have a partial response to the first tablet, or your headache returns, a second tablet may be taken 4 hours after the first tablet. Do not take more than two tablets of naratriptan in any 24-hour period. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take naratriptan exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.









Naratriptan should be taken with plenty of water or other fluids. Always read the manufacturer's information leaflet before beginning treatment.

One tablet should be taken at the onset of a migraine attack. If your migraine is not eased after this first dose, do not take a second dose for the same attack. If your migraine goes away but then returns, you may take a second tablet at least four hours after the initial dose. No more than two tablets should be taken in 24 hours.

Never take more than the prescribed dose. If you suspect that you or someone else has taken an overdose of naratriptan contact your doctor or go to the accident and emergency department of your local hospital at once. Always take the container with you even if it is empty. Naratriptan is for you. Never give it to others, even if their condition appears to be the same as yours.



DRUG DESCRIPTION

- Naratriptan is used to treat the symptoms of migraine headaches (severe, throbbing headaches that sometimes are accompanied by nausea and sensitivity to sound or light). Naratriptan is in a class of medications called selective serotonin receptor agonists. It works by narrowing blood vessels in the brain, stopping pain signals from being sent to the brain, and stopping the release of certain natural substances that cause pain, nausea, and other symptoms of migraine. Naratriptan does not prevent migraine attacks.
 - Naratriptan hydrochloride is a white to pale yellow powder that is readily soluble in water. Each Tablet for oral administration contains 1.11 or 2.78 mg of naratriptan hydrochloride equivalent to 1 or 2.5 mg of naratriptan, respectively. Each tablet also contains the inactive ingredients croscarmellose sodium; hypromellose; lactose; magnesium stearate; microcrystalline cellulose; triacetin; and titanium dioxide, iron oxide yellow (2.5-mg tablet only), and indigo carmine aluminum lake (FD&C Blue No. 2) (2.5-mg tablet only) for coloring.
 - It is thought that the widening of blood vessels in the brain causes the pain associated with migraine. The blood vessels widen on release of a chemical called serotonin. Naratriptan works by binding to receptors in the brain to prevent serotonin from binding. This causes the blood vessels to narrow and relieves the pain felt during a migraine.
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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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