Tizanidine Hcl Cas No.: 64461-82-1

Take this medication by mouth as directed. When you start this medication, your dosage will probably need to be increased slowly by your doctor to reduce side effects, especially dizziness and/or drowsiness. Ask your doctor or pharmacist how to use this medication correctly, and follow all instructions carefully.

Active Pharmaceuticals Ingredients Manufacturers



Taj Pharma PDI



Systematic (IUPAC) name

5-chloro-N-(4,5-dihydro-1H-imidazol-2-yl)-2,1,3-benzothiadiazol-4-amine

Identifiers

Molecular Formula C9H8CIN5S.HCl Molecular Weight 290.17 CAS Registry Number 64461-82-1 ATC code M03BX02 PubChem 5487 DrugBank APRD00128

DOSAGE

How to use

Take this medication by mouth as directed. When you start this medication, your dosage will probably need to be increased slowly by your doctor to reduce side effects, especially dizziness and/or drowsiness. Ask your doctor or pharmacist how to use this medication correctly, and follow all instructions carefully. This medication usually starts to work in 1 to 2 hours and wears off after 6 to 8 hours. Tizanidine can be taken every 6 to 8 hours, but you should not take more than 36 milligrams a day or more than 3 doses in 24 hours. The dosage is based on your medical condition and response to therapy. Your body will absorb this medication differently depending on whether you take it as a tablet or capsule, whether you take it with food or on an empty stomach, or if you sprinkle the contents of the capsule on food. Be sure to discuss this with your doctor to determine the best way to take your dose, especially when changes to your dose are being considered or if your doctor prescribes a different form of tizanidine

SIDE EFFECTS

Nausea, drowsiness, dizziness, constipation, unusual weakness or dry mouth might occur.

If these continue or are bothersome, notify your doctor.

To minimize dizziness, stand up slowly when arising from a sitting or lying position.

Notify your doctor if you develop: yellowing skin or eyes, stomach pain, vomiting, hallucinations.# Very unlikely but report: vision or hearing changes, urinary frequency or burning, slow or irregular heartbeat, black stool.

An allergic reaction to Tizanidine Hcl is unlikely, but seek immediate medical attention if it occurs.

Symptoms of an allergic reaction include rash, itching, dizziness, trouble breathing.

If you notice other effects not listed above, contact your doctor or pharmacist.

Body as a Whole Frequent: Fever

Infrequent: Allergic reaction, moniliasis, malaise, abscess, neck pain, sepsis, cellulites, death, overdos

Rare: Carcinoma, congenital anomaly, suicide attempt

Cardiovascular System

Infrequent: Vasodilatation, postural hypotension, syncope, migraine, arrhythmia

Rare: Angina pectoris, coronary artery disorder, heart failure, myocardial infarct, phlebitis, pulmonary embolus,

ventricular extrasystoles, ventricular tachycardia

Digestive System





Taj Pharmaceuticals Ltd. **Tizanidine <u>H</u>cl**

CAS NO- 64461-82-1

PRECAUTIONS

Before taking tizanidine, 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: low blood pressure or heart disease, kidney disease, liver disease.

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

To minimize dizziness, stand up slowly when arising from a sitting or lying position.

Caution is advised when using this drug in the elderly because they may be more sensitive to its effects, especially dizziness and drowsiness.

This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor.

INTERACTION

Tell your doctor of all prescription and nonprescription medications you may take, especially of: blood pressure drugs (e.g., water pills, clonidine, methyldopa, guanabenz, guanfacine), MAO inhibitors (e.g., linezolid, furazolidone, phenelzine, selegiline), sleep medicines, sedatives (e.g., diazepam), tranquilizers, anti-anxiety drugs, narcotic pain relievers (e.g., codeine, morphine), barbiturates (e.g., phenobarbital), certain antihistamines (e.g., diphenhydramine), other muscle relaxants (e.g., cyclobenzaprine), certain antidepressants (e.g., imipramine, amitriptyline, trazodone), phenothiazine psychiatric drugs (e.g., chlorpromazine), birth control pills, rofecoxib.

Acetaminophen: Tizanidine delayed the Tmax of acetaminophen by 16 minutes. Acetaminophen did not affect the pharmacokinetics of tizanidine.

- Alcohol: Alcohol increased the AUC of tizanidine by approximately 20% while also increasing its Cmax by approximately 15%. This was associated with an increase in side effects of tizanidine. The CNS depressant effects of tizanidine and alcohol are additive.
- Fluvoxamine: Clinically significant hypotension (decreases in both systolic and diastolic pressure) has been reported with concomitant administration of fluvoxamine following single doses of 4 mg.

Caution is recommended when considering concomitant use of tizanidine with other inhibitors of CYP1A2, such as, antiarrhythmics (amiodarone, mexiletine, propafenone), cimetidine, fluoroquinolones (ciprofloxacin, norfloxacin), rofecoxib, oral contraceptives, and ticlopidine.

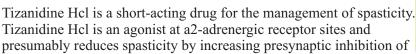
Oral Contraceptives: No specific pharmacokinetic study was conducted to investigate interaction between oral contraceptives and tizanidine, but retrospective analysis of population pharmacokinetic data following single and multiple dose administration of 4 mg tizanidine showed that women concurrently taking oral contraceptives had 50% lower clearance of tizanidine than women not on oral contraceptives.

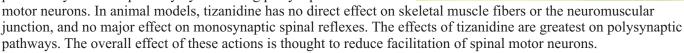




DRUG DESCRIPTION

Tizanidine hydrochloride) is a centrally acting a 2-adrenergic agonist. Tizanidine HCl (tizanidine) is a white to off-white, fine crystalline powder, which is odorless or with a faint characteristic odor. Tizanidine is slightly soluble in water and methanol; solubility in water decreases as the pH increases. Its chemical name is 5-chloro-4-(2-imidazolin-2-ylamino)-2,1,3-benzothiodiazole hydrochloride. tizanidine tablets are composed of the active ingredient, tizanidine hydrochloride (2.29 mg equivalent to 2 mg tizanidine base and 4.58 mg equivalent to 4 mg tizanidine base), and the inactive ingredients, silicon dioxide colloidal, stearic acid, microcrystalline cellulose and anhydrous lactose.







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

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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:

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91 022 30601000.

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