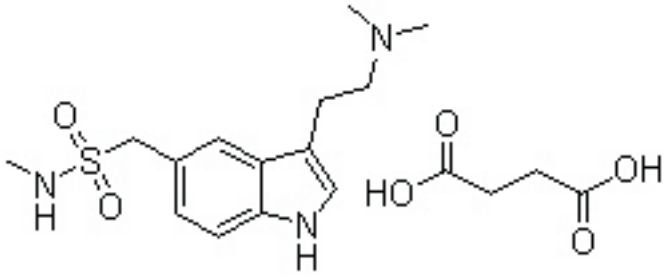
Taj Pharmaceuticals Ltd.

Sumatriptan Succinate

CAS No. : 103628-48-4

Identifiers

Molecular Formula C14H21N3O2S.C4H6O4
Molecular Weight 413.49
CAS Registry Number 103628-48-4



Pharmacokinetic data

Bioavailability 15% (oral)/ 96% (s.c)
Protein binding 14%-21%
Metabolism MAO
Half life 2.5 hours
Excretion 60% urine; 40% feces

DOSAGE

Sumatriptan succinate should be taken as soon as your symptoms appear, but may be used at any time during an attack. It is available in three forms: injection, tablets, and nasal spray.

Sumatriptan succinate injection is administered just below the skin with an autoinjector (self-injection device). Choose a site where the skin is thick enough to take the full length of the needle (1/4 inch). Avoid injecting Sumatriptan succinate into a muscle or a vein. Your doctor should instruct you on how to use the autoinjector and how to dispose of the empty syringes. You should also read the instruction pamphlet that comes with the medication.

You can take a second injection if your headache returns; however, never take more than 2 injections within 24 hours, and be sure to wait 1 hour between doses.

Sumatriptan succinate tablets should be swallowed whole, with liquid. If you have had no relief 2 hours after taking Sumatriptan succinate Tablets, you may take a second dose of up to 100 milligrams, if your doctor advises it. If the headache returns, you may take additional doses at intervals of at least 2 hours. You should not take more than 300 milligrams in one day. If your headache returns after you have had an Sumatriptan succinate Injection, you may take single Sumatriptan succinate Tablets, at intervals of at least 2 hours, up to a maximum of 200 milligrams in a day.

Sumatriptan succinate nasal spray is packaged in single-dose bottles containing either 5 or 20 milligrams of the drug. The usual dosage is a single spray in one nostril. If the headache returns, you may repeat the dose once after 2 hours. Do not take more than 40 milligrams a day.

SIDE EFFECTS

Headache, malaise, dizziness, drowsiness, fatigue, vertigo, anxiety, tight feeling in head, numbness

angina, chest pressure or tightness, transient hypertension, ECG changes, coronary vasospasm, myocardial infarction

vision changes, nasal sinus discomfort, throat discomfort

abdominal discomfort, dysphagia

Musculoskeletal: jaw discomfort, muscle cramps, myalgia, neck pain or stiffness

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Skin: flushing; tingling; warm, cool or, burning sensation

Other: injection site reaction, feeling of heaviness or tightness

Side effects may include:

Burning sensation, dizziness or vertigo, feeling of heaviness, feeling of tightness, flushing, mouth and tongue discomfort, muscle weakness, nausea (nasal spray), neck pain and stiffness, numbness, pressure sensation, redness at the site of injection, sinus or nasal discomfort (nasal spray), sore throat, tingling, unusual taste (nasal spray), vomiting (nasal spray), warm/cold sensation.

PRECAUTIONS

Use cautiously in:
• patients with cardiovascular risk factors (hypertension, hypercholesterolemia, smoking, obesity, diabetes, amily history of cardiovascular disease, men over age 40, menopausal women)
• elderly patients
• women of childbearing age
• pregnant or breastfeeding patients
• children younger than age 18

Before taking sumatriptan, tell your doctor or pharmacist if you are allergic to it; or to other migraine drugs; or if you have any other allergies. Before using this medication, tell your doctor or pharmacist if you have risk factors for heart disease including: high cholesterol level, high blood pressure, diabetes, smoking history, family history of heart disease or stroke, obesity. Caution is also recommended in women after menopause or after removal of the ovaries, and men over 40 years old because of an increased risk for undiagnosed heart disease. Before using this medication, tell your doctor or pharmacist your medical history, especially of: certain blood circulation disorders a heart condition, stroke, chest pain, kidney disease, liver problems, seizures. There have been rare reports of those with sulfa drug allergies having allergic reactions to sumatriptan. Consult your doctor or pharmacist. Because this medication may cause dizziness and drowsiness, use caution engaging in activities requiring alertness. The manufacturer does not recommend use of sumatriptan in the elderly, because they may be more sensitive to its side effects. This medication should be used only when clearly needed if you are pregnant or trying to become pregnant. Discuss the risks and benefits with your doctor. This medication appears in breast milk. Consult your doctor about breast-feeding.

INTERACTION

Certain medications taken with this product could result in serious, even fatal, drug interactions. Do not take MAO inhibitors (e.g., furazolidone, linezolid, phenelzine, procarbazine, selegiline, tranylcypromine) for at least 2 weeks before or after taking this drug. Do not take other "triptan" migraine drugs (e.g., zolmitriptan, rizatriptan) or ergot-type drugs (e.g., dihydroergotamine, ergotamine, methysergide) within 24 hours of taking this medicine. Before using this medication, tell your doctor or pharmacist of all nonprescription and prescription products you may use, especially of: other drugs for prevention or treatment of headaches, "serotonin-type" medications (e.g., SSRI antidepressants such as fluvoxamine, sertraline), medication for weight control. It is recommended to avoid consumption of alcohol while taking this medication.

Dihydroergotamine, ergotamine, methysergide: increased risk of vasospastic reaction

Lithium, MAO inhibitors, selective serotonin reuptake inhibitors: weakness, hyperreflexia, incoordination

DRUG DESCRIPTION

Sumatriptan succinate is a white to off-white powder that is readily soluble in water and in saline. Each Sumatriptan succinate Tablet for oral administration contains 35, 70, or 140 mg of sumatriptan succinate equivalent to 25, 50, or 100 mg of sumatriptan, respectively. Each tablet also contains the inactive ingredients croscarmellose sodium, dibasic calcium phosphate, magnesium stearate, microcrystalline cellulose, and sodium bicarbonate. Each 100-mg tablet also contains hypromellose, iron oxide, titanium dioxide, and triacetin.

Sumatriptan succinate is prescribed for the treatment of a migraine attack with or without the presence of an aura (visual disturbances, usually sensations of halos or flickering lights, which precede an attack). The injectable form is also used to relieve cluster headache attacks. (Cluster headaches come on in waves, then disappear for long periods of time. They are limited to one side of the head, and occur mainly in men.)

Sumatriptan succinate cuts headaches short. It will not reduce the number of attacks you experience.

Sumatriptan succinate should be used only to treat an acute, classic migraine attack or a cluster headache. It should not be used for certain unusual types of migraine.

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 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

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