SUMATRIPTAN SUCCINATE- sumatriptan succinate injection, solution
Teva Parenteral Medicines, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use SUMATRIPTAN SUCCINATE INJECTION safely and effectively. See full prescribing information for SUMATRIPTAN SUCCINATE INJECTION.

Initial U.S. Approval: 1992

INDICATIONS AND USAGE
Sumatriptan Succinate Injection is a serotonin (5-HT_{1B/1D}) receptor agonist (triptan) indicated for:

* Acute treatment of migraine with or without aura in adults (1)
* Acute treatment of cluster headache in adults (1)

Limitations of Use:

* Use only if a clear diagnosis of migraine or cluster headache has been established (1)
* Not indicated for the prophylactic therapy of migraine or cluster headache attacks (1)

DOSAGE AND ADMINISTRATION

* For subcutaneous use only (2.1)
* Acute treatment of migraine: single dose of 1 to 6 mg (2.1)
* Acute treatment of cluster headache: single dose of 6 mg (2.1)
* Maximum dose in a 24-hour period: 12 mg, separate doses by at least 1 hour (2.1)
* Patients receiving doses other than 4 or 6 mg: Use the 6-mg single-dose vial (2.3)

DOSAGE FORMS AND STRENGTHS

* Injection: 6-mg single-dose vial (3)

CONTRAINDICATIONS

* History of coronary artery disease or coronary artery vasospasm (4)
* Wolff-Parkinson-White syndrome or other cardiac accessory conduction pathway disorders (4)
* History of stroke, transient ischemic attack, or hemiplegic or basilar migraine (4)
* Peripheral vascular disease (4)
* Ischemic bowel disease (4)
* Uncontrolled hypertension (4)
* Recent (within 24 hours) use of another 5-HT_{1D} agonist (e.g., another triptan) or of an ergotamine-containing medication (4)
* Concurrent or recent (past 2 weeks) use of monoamine oxidase-A inhibitor (4)
* Hypersensitivity to sumatriptan (angioedema and anaphylaxis seen) (4)
* Severe hepatic impairment (4)

WARNINGS AND PRECAUTIONS

* Myocardial ischemia/infarction and Prinzmetal's angina: Perform cardiac evaluation in patients with multiple cardiovascular risk factors (5.1)
* Arrhythmias: Discontinue sumatriptan succinate injection if occurs (5.2)
* Chest/throat/neck/jaw pain, tightness, pressure, or heaviness: Generally not associated with myocardial ischemia; evaluate for coronary artery disease in patients at high risk (5.3)
* Cerebral hemorrhage, subarachnoid hemorrhage, and stroke: Discontinue sumatriptan succinate if occurs (5.4)
* Gastrointestinal ischemia reactions and peripheral vasospastic reactions: Discontinue sumatriptan succinate if occurs (5.5)
* Medication overuse headache: Detoxification may be necessary (5.6)
* Serotonin syndrome: Discontinue sumatriptan succinate if occurs (5.7)
ADVERSE REACTIONS

Most common adverse reactions (>5% and >placebo) were injection site reactions, tingling, dizziness/vertigo, warm/hot sensation, burning sensation, feeling of heavity, pressure sensation, flushing, feeling of tightness, and numbness (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact TEVA USA, PHARMACOVIGILANCE at 1-866-832-8537 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

USE IN SPECIFIC POPULATIONS

Pregnancy: Based on animal data, may cause fetal harm (8.1)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 12/2015

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1 INDICATIONS AND USAGE

Sumatriptan Succinate Injection is indicated in adults for (1) the acute treatment of migraine, with or without aura, and (2) the acute treatment of cluster headache.

Limitations of Use:

- Use only if a clear diagnosis of migraine or cluster headache has been established. If a patient has no response to the first migraine or cluster headache attack treated with Sumatriptan Succinate Injection, reconsider the diagnosis before Sumatriptan Succinate Injection is administered to treat any subsequent attacks.
- Sumatriptan Succinate Injection is not indicated for the prevention of migraine or cluster headache attacks.

2 DOSAGE AND ADMINISTRATION

2.1 Dosing Information

The maximum single recommended adult dose of sumatriptan succinate injection for the acute treatment of migraine or cluster headache is 6 mg injected subcutaneously. For the treatment of migraine, if side effects are dose limiting, lower doses (1 mg to 5 mg) may be used [see Clinical Studies (14.1)]. For the treatment of cluster headache, the efficacy of lower doses has not been established.

The maximum cumulative dose that may be given in 24 hours is 12 mg, two 6-mg injections separated by at least 1 hour. A second 6-mg dose should only be considered if some response to a first injection was observed.

2.3 Administration of Doses of Sumatriptan Other Than 4 or 6 mg

In patients receiving doses other than 4 mg or 6 mg, use the 6-mg single-dose vial. Visually inspect the vial for particulate matter and discoloration before administration. Do not use if particulates and discolorations are noted.

3 DOSAGE FORMS AND STRENGTHS

Injection: 6-mg single-dose vial.

4 CONTRAINDICATIONS

Sumatriptan succinate injection is contraindicated in patients with:
• Ischemic coronary artery disease (CAD) (angina pectoris, history of myocardial infarction, or documented silent ischemia) or coronary artery vasospasm, including Prinzmetal’s angina [see Warnings and Precautions (5.1)].
• Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders [see Warnings and Precautions (5.2)].
• History of stroke or transient ischemic attack (TIA) or history of hemiplegic or basilar migraine because these patients are at a higher risk of stroke [see Warnings and Precautions (5.4)].
• Peripheral vascular disease [see Warnings and Precautions (5.5)].
• Ischemic bowel disease [see Warnings and Precautions (5.5)].
• Uncontrolled hypertension [see Warnings and Precautions (5.8)].
• Recent use (i.e., within 24 hours) of ergotamine-containing medication, ergot-type medication (such as dihydroergotamine or methysergide), or another 5-hydroxytryptamine₁ (5-HT₁) agonist [see Drug Interactions (7.1, 7.3)].
• Concurrent administration of a monoamine oxidase (MAO)-A inhibitor or recent (within 2 weeks) use of an MAO-A inhibitor [see Drug Interactions (7.2), Clinical Pharmacology (12.3)].
• Hypersensitivity to sumatriptan succinate (angioedema and anaphylaxis seen) [see Warnings and Precautions (5.9)].
• Severe hepatic impairment [see Clinical Pharmacology (12.3)].

5 WARNINGS AND PRECAUTIONS

5.1 Myocardial Ischemia, Myocardial Infarction, and Prinzmetal’s Angina
The use of sumatriptan succinate injection is contraindicated in patients with ischemic or vasospastic CAD. There have been rare reports of serious cardiac adverse reactions, including acute myocardial infarction, occurring within a few hours following administration of sumatriptan succinate injection. Some of these reactions occurred in patients without known CAD. Sumatriptan succinate injection may cause coronary artery vasospasm (Prinzmetal’s angina), even in patients without a history of CAD. Perform a cardiovascular evaluation in triptan-naive patients who have multiple cardiovascular risk factors (e.g., increased age, diabetes, hypertension, smoking, obesity, strong family history of CAD) prior to receiving sumatriptan succinate injection. If there is evidence of CAD or coronary artery vasospasm, sumatriptan succinate injection is contraindicated. For patients with multiple cardiovascular risk factors who have a negative cardiovascular evaluation, consider administering the first dose of sumatriptan succinate injection in a medically supervised setting and performing an electrocardiogram (ECG) immediately following administration of sumatriptan succinate injection. For such patients, consider periodic cardiovascular evaluation in intermittent long-term users of sumatriptan succinate injection.

5.2 Arrhythmias
Life-threatening disturbances of cardiac rhythm, including ventricular tachycardia and ventricular fibrillation leading to death, have been reported within a few hours following the administration of 5-HT₁ agonists. Discontinue sumatriptan succinate injection if these disturbances occur. Sumatriptan succinate injection is contraindicated in patients with Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders.

5.3 Chest, Throat, Neck, and/or Jaw Pain/Tightness/Pressure
Sensations of tightness, pain, pressure, and heaviness in the precordium, throat, neck, and jaw commonly occur after treatment with sumatriptan succinate injection and are usually non-cardiac in origin. However, perform a cardiac evaluation if these patients are at high cardiac risk. The use of sumatriptan succinate injection is contraindicated in patients with CAD and those with Prinzmetal’s variant angina.
5.4 Cerebrovascular Events
Cerebral hemorrhage, subarachnoid hemorrhage, and stroke have occurred in patients treated with 5-HT\textsubscript{1} agonists, and some have resulted in fatalities. In a number of cases, it appears possible that the cerebrovascular events were primary, the 5-HT\textsubscript{1} agonist having been administered in the incorrect belief that the symptoms experienced were a consequence of migraine when they were not. Also, patients with migraine may be at increased risk of certain cerebrovascular events (e.g., stroke, hemorrhage, TIA). Discontinue sumatriptan succinate injection if a cerebrovascular event occurs.

Before treating headaches in patients not previously diagnosed with migraine or cluster headache or in patients who present with atypical symptoms, exclude other potentially serious neurological conditions. Sumatriptan succinate injection is contraindicated in patients with a history of stroke or TIA.

5.5 Other Vasospasm Reactions
Sumatriptan succinate injection may cause non-coronary vasospastic reactions, such as peripheral vascular ischemia, gastrointestinal vascular ischemia and infarction (presenting with abdominal pain and bloody diarrhea), splenic infarction, and Raynaud’s syndrome. In patients who experience symptoms or signs suggestive of non-coronary vasospasm reaction following the use of any 5-HT\textsubscript{1} agonist, rule out a vasospastic reaction before receiving additional sumatriptan succinate injections.

Reports of transient and permanent blindness and significant partial vision loss have been reported with the use of 5-HT\textsubscript{1} agonists. Since visual disorders may be part of a migraine attack, a causal relationship between these events and the use of 5-HT\textsubscript{1} agonists have not been clearly established.

5.6 Medication Overuse Headache
Overuse of acute migraine drugs (e.g., ergotamine, triptans, opioids, or combination of these drugs for 10 or more days per month) may lead to exacerbation of headache (medication overuse headache). Medication overuse headache may present as migraine-like daily headaches, or as a marked increase in frequency of migraine attacks. Detoxification of patients, including withdrawal of the overused drugs, and treatment of withdrawal symptoms (which often includes a transient worsening of headache) may be necessary.

5.7 Serotonin Syndrome
Serotonin syndrome may occur with sumatriptan succinate injection, particularly during co-administration with selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), and MAO inhibitors [see Drug Interactions (7.4)]. Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, coma), autonomic instability (e.g., tachycardia, labile blood pressure, hyperthermia), neuromuscular aberrations (e.g., hyperreflexia, incoordination), and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). The onset of symptoms usually occurs within minutes to hours of receiving a new or a greater dose of a serotonergic medication. Discontinue sumatriptan succinate injection if serotonin syndrome is suspected.

5.8 Increase in Blood Pressure
Significant elevation in blood pressure, including hypertensive crisis with acute impairment of organ systems, has been reported on rare occasions in patients treated with 5-HT\textsubscript{1} agonists, including patients without a history of hypertension. Monitor blood pressure in patients treated with sumatriptan succinate. Sumatriptan succinate injection is contraindicated in patients with uncontrolled hypertension.

5.9 Anaphylactic/Anaphylactoid Reactions
Anaphylactic/anaphylactoid reactions have occurred in patients receiving sumatriptan succinate. Such reactions can be life threatening or fatal. In general, anaphylactic reactions to drugs are more likely to
occur in individuals with a history of sensitivity to multiple allergens. Sumatriptan succinate injection is contraindicated in patients with a history of hypersensitivity reaction to sumatriptan succinate.

5.10 Seizures
Seizures have been reported following administration of sumatriptan succinate. Some have occurred in patients with either a history of seizures or concurrent conditions predisposing to seizures. There are also reports in patients where no such predisposing factors are apparent. Sumatriptan succinate injection should be used with caution in patients with a history of epilepsy or conditions associated with a lowered seizure threshold.

6 ADVERSE REACTIONS
The following serious adverse reactions are described below and elsewhere in the labeling:

- Myocardial ischemia, myocardial infarction, and Prinzmetal’s angina [see Warnings and Precautions (5.1)]
- Arrhythmias [see Warnings and Precautions (5.2)]
- Chest, throat, neck, and/or jaw pain/tightness/pressure [see Warnings and Precautions (5.3)]
- Cerebrovascular events [see Warnings and Precautions (5.4)]
- Other vasospasm reactions [see Warnings and Precautions (5.5)]
- Medication overuse headache [see Warnings and Precautions (5.6)]
- Serotonin syndrome [see Warnings and Precautions (5.7)]
- Increase in blood pressure [see Warnings and Precautions (5.8)]
- Hypersensitivity reactions [see Contraindications (4), Warnings and Precautions (5.9)]
- Seizures [see Warnings and Precautions (5.10)]

6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Migraine Headache
Table 1 lists adverse reactions that occurred in 2 US placebo-controlled clinical trials in migraine patients (Studies 2 and 3) following either a single 6-mg dose of sumatriptan succinate injection or placebo. Only reactions that occurred at a frequency of 2% or more in groups treated with sumatriptan succinate injection 6 mg and that occurred at a frequency greater than the placebo group are included in Table 1.

Table 1. Adverse Reactions in Pooled Placebo-Controlled Trials in Patients with Migraine

(Studies 2 and 3)

<table>
<thead>
<tr>
<th></th>
<th>Sumatriptan Succinate Injection 6 mg Subcutaneous (n = 547) %</th>
<th>Placebo (n = 370) %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atypical sensations</td>
<td>42</td>
<td>9</td>
</tr>
<tr>
<td>Tingling</td>
<td>14</td>
<td>3</td>
</tr>
<tr>
<td>Warm/hot sensation</td>
<td>11</td>
<td>4</td>
</tr>
<tr>
<td>Burning sensation</td>
<td>7</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Symptom</td>
<td>Sumatriptan Succinate</td>
<td>Placebo</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-----------------------</td>
<td>----------</td>
</tr>
<tr>
<td>Feeling of heavity</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Pressure sensation</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>Feeling of tightness</td>
<td>5</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Numbness</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Feeling strange</td>
<td>2</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Tight feeling in head</td>
<td>2</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flushing</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>Chest discomfort</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Tightness in chest</td>
<td>3</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Pressure in chest</td>
<td>2</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Ear, nose, and throat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Throat discomfort</td>
<td>3</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Discomfort: nasal cavity/sinuses</td>
<td>2</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Injection site reaction*</td>
<td>59</td>
<td>24</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jaw discomfort</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Musculoskeletal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weakness</td>
<td>5</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Neck pain/stiffness</td>
<td>5</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Myalgia</td>
<td>2</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Neurological</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dizziness/vertigo</td>
<td>12</td>
<td>4</td>
</tr>
<tr>
<td>Drowsiness/sedation</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Headache</td>
<td>2</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Skin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sweating</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

* Includes injection site pain, stinging/burning, swelling, erythema, bruising, bleeding.

The incidence of adverse reactions in controlled clinical trials was not affected by gender or age of the patients. There were insufficient data to assess the impact of race on the incidence of adverse reactions.

**Cluster Headache**

In the controlled clinical trials assessing the efficacy of sumatriptan succinate injection as a treatment for cluster headache (Studies 4 and 5), no new significant adverse reactions were detected that had not already been identified in trials of sumatriptan succinate in patients with migraine.

Overall, the frequency of adverse reactions reported in the trials of cluster headache was generally lower than in the migraine trials. Exceptions include reports of paresthesia (5% sumatriptan succinate, 0% placebo), nausea and vomiting (4% sumatriptan succinate, 0% placebo), and bronchospasm (1% sumatriptan succinate, 0% placebo).

### 6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of sumatriptan succinate injection. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

**Cardiovascular**

Hypotension, palpitations.

**Neurological**
7 DRUG INTERACTIONS

7.1 Ergot-containing Drugs
Ergot-containing drugs have been reported to cause prolonged vasospastic reactions. Because these effects may be additive, use of ergotamine-containing or ergot-type medications (like dihydroergotamine or methysergide) and sumatriptan succinate injection within 24 hours of each other is contraindicated.

7.2 Monoamine Oxidase-A Inhibitors
MAO-A inhibitors increase systemic exposure by 2-fold. Therefore, the use of sumatriptan succinate injection in patients receiving MAO-A inhibitors is contraindicated [see Clinical Pharmacology (12.3)].

7.3 Other 5-HT₁ Agonists
Because their vasospastic effects may be additive, co-administration of sumatriptan succinate injection and other 5-HT₁ agonists (e.g., triptans) within 24 hours of each other is contraindicated.

7.4 Selective Serotonin Reuptake Inhibitors/Serotonin Norepinephrine Reuptake Inhibitors and Serotonin Syndrome
Cases of serotonin syndrome have been reported during co-administration of triptans and SSRIs, SNRIs, TCAs, and MAO inhibitors [see Warnings and Precautions (5.7)].

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic Effects
Pregnancy Category C

There are no adequate and well-controlled trials of sumatriptan succinate injection in pregnant women. In developmental toxicity studies in rats and rabbits, oral administration of sumatriptan to pregnant animals was associated with embryolethality, fetal abnormalities, and pup mortality. When administered by the intravenous route to pregnant rabbits, sumatriptan was embryolethal. Sumatriptan succinate injection should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Oral administration of sumatriptan to pregnant rats during the period of organogenesis resulted in an increased incidence of fetal blood vessel (cervicothoracic and umbilical) abnormalities. The highest no-effect dose for embryofetal developmental toxicity in rats was 60 mg/kg/day, or approximately 100 times the single maximum recommended human dose (MRHD) of 6 mg administered subcutaneously on a mg/m² basis. Oral administration of sumatriptan to pregnant rabbits during the period of organogenesis resulted in increased incidences of embryolethality and fetal cervicothoracic vascular and skeletal abnormalities. Intravenous administration of sumatriptan to pregnant rabbits during the period of organogenesis resulted in an increased incidence of embryolethality. The highest oral and intravenous no-effect doses for developmental toxicity in rabbits were 15 and 0.75 mg/kg/day, or approximately 50 and 2 times, respectively, the single MRHD of 6 mg administered subcutaneously on a mg/m² basis.

Oral administration of sumatriptan to rats prior to and throughout gestation resulted in embryofetal toxicity (decreased body weight, decreased ossification, increased incidence of skeletal abnormalities). The highest no-effect dose was 50 mg/kg/day, or approximately 80 times the single MRHD of 6 mg administered subcutaneously on a mg/m² basis. In offspring of pregnant rats treated orally with sumatriptan during organogenesis, there was a decrease in pup survival. The highest no-effect dose for
during organogenesis, there was a decrease in pup survival. The highest no-effect dose for this effect was 60 mg/kg/day, or approximately 100 times the single MRHD of 6 mg administered subcutaneously on a mg/m² basis. Oral treatment of pregnant rats with sumatriptan during the latter part of gestation and throughout lactation resulted in a decrease in pup survival. The highest no-effect dose for this finding was 100 mg/kg/day, or approximately 160 times the single MRHD of 6 mg administered subcutaneously on a mg/m² basis.

8.3 Nursing Mothers

Sumatriptan is excreted in human milk following subcutaneous administration. Infant exposure to sumatriptan can be minimized by avoiding breastfeeding for 12 hours after treatment with sumatriptan succinate injection.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established. Sumatriptan succinate injection is not recommended for use in patients younger than 18 years of age.

Postmarketing experience documents that serious adverse reactions have occurred in the pediatric population after use of subcutaneous, oral, and/or intranasal sumatriptan. These reports include reactions similar in nature to those reported rarely in adults, including stroke, visual loss, and death. A myocardial infarction has been reported in a 14-year-old male following the use of oral sumatriptan; clinical signs occurred within 1 day of drug administration. Clinical data to determine the frequency of serious adverse reactions in pediatric patients who might receive subcutaneous, oral, or intranasal sumatriptan are not presently available.

8.5 Geriatric Use

Clinical trials of sumatriptan succinate injection did not include sufficient numbers of patients 65 years of age and older to determine whether they respond differently from younger patients. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy.

A cardiovascular evaluation is recommended for geriatric patients who have other cardiovascular risk factors (e.g., diabetes, hypertension, smoking, obesity, strong family history of CAD) prior to receiving sumatriptan succinate injection [see Warnings and Precautions (5.1)].

10 OVERDOSAGE

Coronary vasospasm was observed after intravenous administration of sumatriptan succinate injection [see Contraindications (4)]. Overdoses would be expected from animal data (dogs at 0.1 g/kg, rats at 2 g/kg) to possibly cause convulsions, tremor, inactivity, erythema of the extremities, reduced respiratory rate, cyanosis, ataxia, mydriasis, injection site reactions (desquamation, hair loss, and scab formation), and paralysis.

The elimination half-life of sumatriptan is about 2 hours [see Clinical Pharmacology (12.3)]; therefore, monitoring of patients after overdose with sumatriptan succinate injection should continue for at least 10 hours or while symptoms or signs persist.

It is unknown what effect hemodialysis or peritoneal dialysis has on the serum concentrations of sumatriptan.

11 DESCRIPTION

Sumatriptan Succinate Injection is a selective 5-hydroxytryptamine1 receptor subtype agonist. Sumatriptan succinate, USP is chemically designated as 3-[2-(dimethylamino)ethyl]-N-methyl-indole-5-
methanesulfonamide succinate (1:1), and it has the following structure:

![Chemical Structure](image)

C₁₄H₂₁N₃O₂S•C₄H₆O₄ M.W. 413.5

Sumatriptan succinate, USP is a white to off-white powder that is readily soluble in water and in saline. Sumatriptan Succinate Injection is a clear, colorless to pale yellow, sterile, nonpyrogenic solution for subcutaneous injection. Each 0.5 mL of Sumatriptan Succinate Injection 12 mg/mL solution contains 6 mg of sumatriptan (base) as the succinate salt and 3.5 mg of sodium chloride in water for injection. The pH range of the solution is approximately 4.2 to 5.3. The osmolality of the injection is 270 to 330 mOsmol.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action
Sumatriptan binds with high affinity to human cloned 5-HT₁B/₁D receptors. Sumatriptan presumably exerts its therapeutic effects in the treatment of migraine and cluster headaches through agonist effects at the 5-HT₁B/₁D receptors on intracranial blood vessels and sensory nerves of the trigeminal system, which result in cranial vessel constriction and inhibition of pro-inflammatory neuropeptide release.

12.2 Pharmacodynamics

Blood Pressure
Significant elevation in blood pressure, including hypertensive crisis, has been reported in patients with and without a history of hypertension [see Warnings and Precautions (5.8)].

Peripheral (Small) Arteries
In healthy volunteers (N = 18), a trial evaluating the effects of sumatriptan on peripheral (small vessel) arterial reactivity failed to detect a clinically significant increase in peripheral resistance.

Heart Rate
Transient increases in blood pressure observed in some patients in clinical trials carried out during sumatriptan’s development as a treatment for migraine were not accompanied by any clinically significant changes in heart rate.

12.3 Pharmacokinetics

Absorption and Bioavailability
The bioavailability of sumatriptan via subcutaneous site injection to 18 healthy male subjects was 97% ± 16% of that obtained following intravenous injection.

After a single 6-mg subcutaneous manual injection into the deltoid area of the arm in 18 healthy males (age: 24 ± 6 years, weight: 70 kg), the maximum serum concentration (Cₘₐₓ) of sumatriptan was (mean ± standard deviation) 74 ± 15 ng/mL and the time to peak concentration (Tₘₐₓ) was 12 minutes after injection (range: 5 to 20 minutes). In this trial, the same dose injected subcutaneously in the thigh gave a Cₘₐₓ of 61 ± 15 ng/mL by manual injection versus 52 ± 15 ng/mL by autoinjector techniques. The Tₘₐₓ
or amount absorbed was not significantly altered by either the site or technique of injection.

Distribution

Protein binding, determined by equilibrium dialysis over the concentration range of 10 to 1,000 ng/mL is low, approximately 14% to 21%. The effect of sumatriptan on the protein binding of other drugs has not been evaluated.

Following a 6-mg subcutaneous injection into the deltoid area of the arm in 9 males (mean age: 33 years, mean weight: 77 kg) the volume of distribution central compartment of sumatriptan was 50 ± 8 liters and the distribution half-life was 15 ± 2 minutes.

Metabolism

In vitro studies with human microsomes suggest that sumatriptan is metabolized by MAO, predominantly the A isoenzyme. Most of a radiolabeled dose of sumatriptan excreted in the urine is the major metabolite indole acetic acid (IAA) or the IAA glucuronide, both of which are inactive.

Elimination

After a single 6-mg subcutaneous dose, 22% ± 4% was excreted in the urine as unchanged sumatriptan and 38% ± 7% as the IAA metabolite.

Following a 6-mg subcutaneous injection into the deltoid area of the arm, the systemic clearance of sumatriptan was 1,194 ± 149 mL/min and the terminal half-life was 115 ± 19 minutes.

Specific Populations

Age

The pharmacokinetics of sumatriptan in the elderly (mean age: 72 years, 2 males and 4 females) and in subjects with migraine (mean age: 38 years, 25 males and 155 females) were similar to that in healthy male subjects (mean age: 30 years).

Hepatic Impairment

The effect of mild to moderate hepatic disease on the pharmacokinetics of subcutaneously administered sumatriptan has been evaluated. There were no significant differences in the pharmacokinetics of subcutaneously administered sumatriptan in moderately hepatically impaired subjects compared with healthy controls. The pharmacokinetics of subcutaneously administered sumatriptan in patients with severe hepatic impairment has not been studied. The use of sumatriptan succinate injection in this population is contraindicated [see Contraindications (4)].

Race

The systemic clearance and C$_{\text{max}}$ of subcutaneous sumatriptan were similar in black (n = 34) and Caucasian (n = 38) healthy male subjects.

Drug Interaction Studies

Monoamine Oxidase-A Inhibitors

In a trial of 14 healthy females, pretreatment with an MAO-A inhibitor decreased the clearance of subcutaneous sumatriptan, resulting in a 2-fold increase in the area under the sumatriptan plasma concentration-time curve (AUC), corresponding to a 40% increase in elimination half-life.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

In carcinogenicity studies in mouse and rat in which sumatriptan was administered orally for 78 weeks and 104 weeks, respectively, at doses up to 160 mg/kg/day (the highest dose in rat was reduced from
and 104 weeks, respectively, at doses up to 160 mg/kg/day (the highest dose in rat was reduced from 360 mg/kg/day during Week 21). The highest dose to mice and rats was approximately 130 and 260 times the single MRHD of 6 mg administered subcutaneously on a mg/m² basis. There was no evidence in either species of an increase in tumors related to sumatriptan administration.

**Mutagenesis**

Sumatriptan was negative in *in vitro* (bacterial reverse mutation [Ames], gene cell mutation in Chinese hamster V79/HGPRT, chromosomal aberration in human lymphocytes) and *in vivo* (rat micronucleus) assays.

**Impairment of Fertility**

When sumatriptan was administered by subcutaneous injection to male and female rats prior to and throughout the mating period, there was no evidence of impaired fertility at doses up to 60 mg/kg/day or approximately 100 times the single human dose of 6 mg on a mg/m² basis. When sumatriptan (5, 50, 500 mg/kg/day) was administered orally to male and female rats prior to and throughout the mating period, there was a treatment-related decrease in fertility secondary to a decrease in mating in animals treated with doses greater than 5 mg/kg/day. It is not clear whether this finding was due to an effect on males or females or both.

**13.2 Animal Toxicology and/or Pharmacology**

**Corneal Opacities**

Dogs receiving oral sumatriptan developed corneal opacities and defects in the corneal epithelium. Corneal opacities were seen at the lowest dose tested, 2 mg/kg/day, and were present after 1 month of treatment. Defects in the corneal epithelium were noted in a 60-week study. Earlier examinations for these toxicities were not conducted and no-effect doses were not established; however, the relative plasma exposure at the lowest dose tested was approximately 3 times the human exposure after a 6-mg subcutaneous dose.

**14 CLINICAL STUDIES**

**14.1 Migraine**

In controlled clinical trials enrolling more than 1,000 patients during migraine attacks who were experiencing moderate or severe pain and 1 or more of the symptoms enumerated in Table 3, onset of relief began as early as 10 minutes following a 6-mg sumatriptan succinate injection. Lower doses of sumatriptan succinate injection may also prove effective, although the proportion of patients obtaining adequate relief was decreased and the latency to that relief is greater with lower doses.

In Study 1, 6 different doses of sumatriptan succinate injection (n = 30 each group) were compared with placebo (n = 62), in a single-attack, parallel-group design, the dose-response relationship was found to be as shown in Table 2.

**Table 2. Proportion of Patients with Migraine Relief and Incidence of Adverse Reactions**

<table>
<thead>
<tr>
<th>Dose of Sumatriptan Succinate Injection</th>
<th>Percent Patients with Relief*</th>
<th>Adverse Reactions Incidence (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>at 10 Minutes</td>
<td>at 30 Minutes</td>
</tr>
<tr>
<td>Placebo</td>
<td>5</td>
<td>15</td>
</tr>
<tr>
<td>1 mg</td>
<td>10</td>
<td>40</td>
</tr>
<tr>
<td>2 mg</td>
<td>7</td>
<td>23</td>
</tr>
<tr>
<td>3 mg</td>
<td>17</td>
<td>47</td>
</tr>
</tbody>
</table>
In 2 randomized, placebo-controlled clinical trials of sumatriptan succinate injection 6 mg in 1,104 patients with moderate or severe migraine pain (Studies 2 and 3), the onset of relief was less than 10 minutes. Headache relief, as defined by a reduction in pain from severe or moderately severe to mild or no headache, was achieved in 70% of the patients within 1 hour of a single 6-mg subcutaneous dose of sumatriptan succinate injection. Approximately 82% and 65% of patients treated with sumatriptan 6 mg had headache relief and were pain free within 2 hours, respectively.

Table 3 shows the 1- and 2-hour efficacy results for sumatriptan injection 6 mg in Studies 2 and 3.

**Table 3. Proportion of Patients with Pain Relief and Relief of Migraine Symptoms after 1 and 2 Hours of Treatment in Studies 2 and 3**

<table>
<thead>
<tr>
<th></th>
<th>Study 2</th>
<th>Study 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Placebo (n = 190)</td>
<td>Sumatriptan 6 mg (n = 384)</td>
</tr>
<tr>
<td>Patients with pain relief (grade 0/1)</td>
<td>18%</td>
<td>70%†</td>
</tr>
<tr>
<td>Patients with no pain</td>
<td>5%</td>
<td>48%†</td>
</tr>
<tr>
<td>Patients without nausea</td>
<td>48%</td>
<td>73%†</td>
</tr>
<tr>
<td>Patients without photophobia</td>
<td>23%</td>
<td>56%†</td>
</tr>
<tr>
<td>Patients with little or no clinical disability*</td>
<td>34%</td>
<td>76%†</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Study 2</th>
<th>Study 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Placebo‡</td>
<td>Sumatriptan 6 mg§</td>
</tr>
<tr>
<td>Patients with pain relief (grade 0/1)</td>
<td>31%</td>
<td>81%†</td>
</tr>
<tr>
<td>Patients with no pain</td>
<td>11%</td>
<td>63%†</td>
</tr>
<tr>
<td>Patients without nausea</td>
<td>56%</td>
<td>82%†</td>
</tr>
<tr>
<td>Patients without photophobia</td>
<td>31%</td>
<td>72%†</td>
</tr>
<tr>
<td>Patients with little or no clinical disability*</td>
<td>42%</td>
<td>85%†</td>
</tr>
</tbody>
</table>

* A successful outcome in terms of clinical disability was defined prospectively as ability to work mildly impaired or ability to work and function normally.
† P<0.05 versus placebo.
‡ Includes patients that may have received an additional placebo injection 1 hour after the initial injection.
§ Includes patients that may have received an additional 6 mg of sumatriptan injection 1 hour after the initial injection.

Sumatriptan succinate injection also relieved photophobia, phonophobia (sound sensitivity), nausea, and vomiting associated with migraine attacks.

The efficacy of sumatriptan succinate injection was unaffected by whether or not the migraine was associated with aura, duration of attack, gender or age of the patient, or concomitant use of common migraine prophylactic drugs (e.g., beta-blockers).

**14.2 Cluster Headache**
The efficacy of sumatriptan succinate injection in the acute treatment of cluster headache was demonstrated in 2 randomized, double-blind, placebo-controlled, 2-period crossover trials (Studies 4 and 5). Patients 21 to 65 years of age were enrolled and were instructed to treat a moderate to very severe headache within 10 minutes of onset. Headache relief was defined as a reduction in headache severity to mild or no pain. In both trials, the proportion of individuals gaining relief at 10 or 15 minutes was significantly greater among patients receiving 6 mg of sumatriptan succinate injection compared with those who received placebo (see Table 4).

### Table 4. Proportion of Patients with Cluster Headache Relief by Time in Studies 4 and 5

<table>
<thead>
<tr>
<th></th>
<th>Study 4</th>
<th></th>
<th>Study 5</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Placebo (n = 39)</td>
<td>Sumatriptan 6 mg (n = 39)</td>
<td>Placebo (n = 88)</td>
<td>Sumatriptan 6 mg (n = 92)</td>
</tr>
<tr>
<td>Patients with pain relief (no/mild)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 Minutes post-injection</td>
<td>8%</td>
<td>21%</td>
<td>7%</td>
<td>23%*</td>
</tr>
<tr>
<td>10 Minutes post-injection</td>
<td>10%</td>
<td>49%*</td>
<td>25%</td>
<td>49%*</td>
</tr>
<tr>
<td>15 Minutes post-injection</td>
<td>26%</td>
<td>74%*</td>
<td>35%</td>
<td>75%*</td>
</tr>
</tbody>
</table>

* P<0.05.

An estimate of the cumulative probability of a patient with a cluster headache obtaining relief after being treated with either sumatriptan succinate injection or placebo is presented in Figure 1.

**Figure 1. Time to Relief of Cluster Headache from Time of Injection**

[Graph showing Kaplan-Meier survivorship plot]

1. The figure uses Kaplan-Meier (product limit) Survivorship Plot. Patients taking rescue medication were censored at 15 minutes.

The plot was constructed with data from patients who either experienced relief or did not require (request) rescue medication within a period of 2 hours following treatment. As a consequence, the data
in the plot are derived from only a subset of the 258 headaches treated (rescue medication was required in 52 of the 127 placebo-treated headaches and 18 of the 131 headaches treated with sumatriptan succinate injection).

Other data suggest that treatment with sumatriptan succinate injection is not associated with an increase in early recurrence of headache and has little effect on the incidence of later-occurring headaches (i.e., those occurring after 2, but before 18 or 24 hours).

16 HOW SUPPLIED/STORAGE AND HANDLING
Sumatriptan Succinate Injection 6 mg/0.5 mL containing sumatriptan 6-mg (base) as the succinate salt is supplied as a clear, colorless to pale yellow, sterile, nonpyrogenic solution as follows:

<table>
<thead>
<tr>
<th>NDC Number</th>
<th>Sumatriptan Succinate Injection</th>
<th>Packaged</th>
</tr>
</thead>
<tbody>
<tr>
<td>0703-7351-02</td>
<td>6-mg Single-dose vials</td>
<td>in cartons of 5 vials.</td>
</tr>
</tbody>
</table>

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature]. May be refrigerated. Protect from light.

17 PATIENT COUNSELING INFORMATION
Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

Risk of Myocardial Ischemia and/or Infarction, Prinzmetal’s Angina, Other Vasospasm-Related Events, Arrhythmias, and Cerebrovascular Events
Inform patients that sumatriptan succinate injection may cause serious cardiovascular side effects such as myocardial infarction or stroke. Although serious cardiovascular events can occur without warning symptoms, patients should be alert for the signs and symptoms of chest pain, shortness of breath, irregular heartbeat, significant rise in blood pressure, weakness, and slurring of speech, and should ask for medical advice if any indicative sign or symptoms are observed. Apprise patients of the importance of this follow-up [see Warnings and Precautions (5.1, 5.2, 5.4, 5.5, 5.8)].

Anaphylactic/Anaphylactoid Reactions
Inform patients that anaphylactic/anaphylactoid reactions have occurred in patients receiving sumatriptan succinate injection. Such reactions can be life threatening or fatal. In general, anaphylactic reactions to drugs are more likely to occur in individuals with a history of sensitivity to multiple allergens [see Contraindications (4), Warnings and Precautions (5.9)].

Concomitant Use with Other Triptans or Ergot Medications
Inform patients that use of sumatriptan succinate injection within 24 hours of another triptan or an ergot-type medication (including dihydroergotamine or methysergide) is contraindicated [see Contraindications (4), Drug Interactions (7.1, 7.3)].

Serotonin Syndrome
Caution patients about the risk of serotonin syndrome with the use of sumatriptan succinate injection or other triptans, particularly during combined use with SSRIs, SNRIs, TCAs, and MAO inhibitors [see Warnings and Precautions (5.7), Drug Interactions (7.4)].

Medication Overuse Headache
Inform patients that use of acute migraine drugs for 10 or more days per month may lead to an exacerbation of headache and encourage patients to record headache frequency and drug use (e.g., by keeping a headache diary) [see Warnings and Precautions (5.6)].
Pregnancy
Inform patients that sumatriptan succinate injection should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus [see Use in Specific Populations (8.1)].

Nursing Mothers
Advise patients to notify their healthcare provider if they are breastfeeding or plan to breastfeed [see Use in Specific Populations (8.3)].

Ability to Perform Complex Tasks
Treatment with sumatriptan succinate injection may cause somnolence and dizziness; instruct patients to evaluate their ability to perform complex tasks after administration of sumatriptan succinate injection.

How to Use Sumatriptan Succinate Injection
Provide patients instruction on the proper use of sumatriptan succinate injection if they are able to self-administer sumatriptan succinate injection in medically unsupervised situations.

TEVA PHARMACEUTICALS USA, INC.
North Wales, PA 19454
Rev. A 12/2015

Patient Information
Sumatriptan Succinate
(soo" ma trip' tan sux' i nate)
Injection
Read this Patient Information before you start taking sumatriptan succinate injection and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

What is the most important information I should know about sumatriptan succinate injection?
Sumatriptan succinate injection can cause serious side effects, including:
Heart attack and other heart problems. Heart problems may lead to death.
Stop taking sumatriptan succinate injection and get emergency medical help right away if you have any of the following symptoms of a heart attack:

- discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back
- severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
- pain or discomfort in your arms, back, neck, jaw, or stomach
- shortness of breath with or without chest discomfort
- breaking out in a cold sweat
- nausea or vomiting
- feeling lightheaded

Sumatriptan succinate injection is not for people with risk factors for heart disease unless a heart exam is done and shows no problem. You have a higher risk for heart disease if you:

- have high blood pressure
- have high cholesterol levels
What is sumatriptan succinate injection?

Sumatriptan succinate injection is a prescription medicine used to treat acute migraine headaches with or without aura and acute cluster headaches in adults who have been diagnosed with migraine or cluster headaches.

Sumatriptan succinate injection is not used to treat other types of headaches such as hemiplegic (that make you unable to move on one side of your body) or basilar (rare form of migraine with aura) migraines.

Sumatriptan succinate injection is not used to prevent or decrease the number of migraine or cluster headaches you have.

It is not known if sumatriptan succinate injection is safe and effective in children under 18 years of age.

Who should not take sumatriptan succinate injection?

Do not take sumatriptan succinate injection if you have:

- heart problems or a history of heart problems
- narrowing of blood vessels to your legs, arms, stomach, or kidneys (peripheral vascular disease)
- uncontrolled high blood pressure
- severe liver problems
- hemiplegic migraines or basilar migraines. If you are not sure if you have these types of migraines, ask your healthcare provider.
- had a stroke, transient ischemic attacks (TIAs), or problems with your blood circulation
- taken any of the following medicines in the last 24 hours:
  - almotriptan (AXERT®)
  - eletriptan (RELPAX®)
  - frovatriptan (FROVA®)
  - naratriptan (AMERGE®)
  - rizatriptan (MAXALT®, MAXALT-MLT®)
  - sumatriptan and naproxen (TREXIMET®)
  - ergotamines (CAFERGOT®, ERGOMAR®, MIGERGOT®)
  - dihydroergotamine (D.H.E. 45®, MIGRANAL®)

Ask your healthcare provider if you are not sure if your medicine is listed above.

- an allergy to sumatriptan or any of the ingredients in sumatriptan succinate injection. See the end of this leaflet for a complete list of ingredients in sumatriptan succinate injection.

What should I tell my healthcare provider before taking sumatriptan succinate injection?

Before you take sumatriptan succinate injection, tell your healthcare provider about all of your medical conditions, including if you:

- have high blood pressure
- have high cholesterol
• have diabetes
• smoke
• are overweight
• have heart problems or family history of heart problems or stroke
• have kidney problems
• have liver problems
• have had epilepsy or seizures
• are not using effective birth control
• become pregnant while taking sumatriptan succinate injection
• are breastfeeding or plan to breastfeed. Sumatriptan succinate injection passes into your breast milk and may harm your baby. Talk with your healthcare provider about the best way to feed your baby if you take sumatriptan succinate injection.

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

Sumatriptan succinate injection and certain other medicines can affect each other, causing serious side effects.

Especially tell your healthcare provider if you take anti-depressant medicines called:

• selective serotonin reuptake inhibitors (SSRIs)
• serotonin norepinephrine reuptake inhibitors (SNRIs)
• tricyclic antidepressants (TCAs)
• monoamine oxidase inhibitors (MAOIs)

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure.

Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

How should I take sumatriptan succinate injection?

• Certain people should take their first dose of sumatriptan succinate injection in their healthcare provider’s office or in another medical setting. Ask your healthcare provider if you should take your first dose in a medical setting.
• Use sumatriptan succinate injection exactly as your healthcare provider tells you to use it.
• Your healthcare provider may change your dose. Do not change your dose without first talking with your healthcare provider.
• For adults, the usual dose is a single injection given just below the skin.
• You should give an injection as soon as the symptoms of your headache start, but it may be given at any time during a migraine or cluster headache attack.
• If you did not get any relief after the first injection, do not give a second injection without first talking with your healthcare provider.
• If your headache comes back or you only get some relief after your first injection, you can take a second injection 1 hour after the first injection, but not sooner.
• Do not take more than 12 mg in a 24-hour period.
• If you use too much sumatriptan succinate injection, call your healthcare provider or go to the nearest hospital emergency room right away.
• You should write down when you have headaches and when you take sumatriptan succinate injection so you can talk with your healthcare provider about how sumatriptan succinate injection is working for you.
What should I avoid while taking sumatriptan succinate injection?

Sumatriptan succinate injection can cause dizziness, weakness, or drowsiness. If you have these symptoms, do not drive a car, use machinery, or do anything where you need to be alert.

What are the possible side effects of sumatriptan succinate injection?

**Sumatriptan succinate injection may cause serious side effects.** See “What is the most important information I should know about sumatriptan succinate injection?”

These serious side effects include:

- changes in color or sensation in your fingers and toes (Raynaud’s syndrome)
- stomach and intestinal problems (gastrointestinal and colonic ischemic events).
  - Symptoms of gastrointestinal and colonic ischemic events include:
    - sudden or severe stomach pain
    - stomach pain after meals
    - weight loss
    - nausea or vomiting
    - constipation or diarrhea
    - bloody diarrhea
    - fever
- problems with blood circulation to your legs and feet (peripheral vascular ischemia). Symptoms of peripheral vascular ischemia include:
  - cramping and pain in your legs or hips
  - feeling of heaviness or tightness in your leg muscles
  - burning or aching pain in your feet or toes while resting
  - numbness, tingling, or weakness in your legs
  - cold feeling or color changes in 1 or both legs or feet
- hives (itchy bumps); swelling of your tongue, mouth, or throat
- medication overuse headaches. Some people who use too many sumatriptan succinate injections may have worse headaches (medication overuse headache). If your headaches get worse, your healthcare provider may decide to stop your treatment with sumatriptan succinate injection.
- serotonin syndrome. Serotonin syndrome is a rare but serious problem that can happen in people using sumatriptan succinate injection, especially if sumatriptan succinate injection is used with anti-depressant medicines called SSRIs or SNRIs.
  - Call your healthcare provider right away if you have any of the following symptoms of serotonin syndrome:
    - mental changes such as seeing things that are not there (hallucinations), agitation, or coma
    - fast heartbeat
    - changes in blood pressure
    - high body temperature
    - tight muscles
    - trouble walking
The most common side effects of sumatriptan succinate injection include:

- pain or redness at your injection site
- tingling or numbness in your fingers or toes
- dizziness
- warm, hot, burning feeling to your face (flushing)
- discomfort or stiffness in your neck
- feeling weak, drowsy, or tired

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of sumatriptan succinate injection. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store sumatriptan succinate injection?

- Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F).
- Store your medicine away from light.
- Keep your medicine in the packaging or carrying case provided with it.

Keep sumatriptan succinate injection and all medicines out of the reach of children.

General information about the safe and effective use of sumatriptan succinate injection

Medicines are sometimes prescribed for purposes other than those listed in Patient Information leaflets. Do not use sumatriptan succinate injection for a condition for which it was not prescribed. Do not give sumatriptan succinate injection to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about sumatriptan succinate injection. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about sumatriptan succinate injection that is written for healthcare professionals.

For more information call 1-888-838-2872.

What are the ingredients in sumatriptan succinate injection?

Active ingredient: sumatriptan succinate

Inactive ingredients: sodium chloride, water for injection

This Patient Information and Instructions for Use has been approved by the U.S. Food and Drug Administration.

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TEVA PHARMACEUTICALS USA, INC.

North Wales, PA 19454

Rev. A 12/2015
**SUMATRIPTAN SUCCINATE**  
sumatriptan succinate injection, solution

### Product Information

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<td>Route of Administration</td>
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### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
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<tbody>
<tr>
<td>SUMATRIPTAN SUCCINATE</td>
<td>SUMATRIPTAN</td>
<td>6 mg in 0.5 mL</td>
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### Inactive Ingredients

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<tr>
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<td>SODIUM CHLORIDE</td>
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### Packaging

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### Marketing Information

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<td>ANDA077907</td>
<td>02/06/2009</td>
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**Labeler** - Teva Parenteral Medicines, Inc. (794362533)

Revised: 12/2015