Sumatriptan Succinate Injection

**STORAGE**
Store at room temperature (20°C to 25°C), and protected from light. Do not freeze. Avoid exposure to temperatures below 2°C or above 30°C. If the integrity of the glass ampoule is compromised, do not use the ampoule. After reconstitution, use the solution within 12 hours in a refrigerator or room temperature. Store the vials at room temperature (15°C to 30°C) with the vial cap on until use. Do not discard the vial cap.

**INDICATIONS**
Sumatriptan succinate injection is indicated for 1) the acute treatment of migraine headache in adults 2) the acute treatment of cluster headache in adults. It is also indicated as an add-on prophylactic medication in adult patients with migraine headaches, alone or in combination with other prophylactic medications.

**CONTRAINDICATIONS**
Sumatriptan succinate should be avoided in patients who have suffered a recent myocardial infarction, unstable angina, or a stroke within the last 6 months. It is also contraindicated in patients who have had a recent coronary artery bypass surgery or a coronary angioplasty, or who have significant coronary artery disease as determined by physical examination, history, or ECG. It is not recommended for use in patients with a history of severe head injury, intracranial blood pressure, or intracranial disease. It is also contraindicated in patients with a history of closure of the ductus arteriosus, or who have a history of prior anaphylactic reaction to sumatriptan or any of the ingredients of the injection.

**WARNINGS**
Drug-Associated Cardiac Events and Fatalities: Migraine headache attacks may occasionally be associated with, or exacerbate, pre-existing cardiovascular conditions. This can lead to life-threatening cardiac events. Migraine patients with known cardiac disease or risk factors for cardiac disease, such as hypertension, high cholesterol, diabetes, smoking, or obesity, should be evaluated by a healthcare provider before starting treatment with sumatriptan. If a patient experiences signs or symptoms suggestive of angina following sumatriptan, they should be evaluated by a healthcare provider.

**ADVERSE REACTIONS**
The adverse events associated with the use of sumatriptan succinate injection include: Headache, chest pain, back pain, neck pain, and upper abdominal pain. Other adverse reactions include flu-like symptoms, flushing, hot flashes, and skin reactions. The most common adverse reactions are chest pain, flushing, hot flashes, and skin reactions.

**INTERACTIONS**
Sumatriptan may interact with drugs that affect the heart's rhythm, such as beta blockers, calcium channel blockers, or certain anti-arrhythmic drugs. It may also interact with other medications, such as antiplatelet drugs, anti-coagulants, or other medications for the treatment of migraine or cluster headache.

**CLINICAL PHARMACOLOGY**
Sumatriptan succinate injection is a selective 5-hydroxytryptamine (5-HT1) receptor agonist, with a high degree of affinity for the 5-HT1B and 5-HT1D receptors. It is rapidly absorbed following subcutaneous injection, with peak plasma concentrations achieved within 30 to 60 minutes. The elimination half-life of sumatriptan is approximately 2 hours.

**PHARMACOKINETICS**
Following subcutaneous administration, sumatriptan succinate is metabolized in the liver, primarily by CYP3A4, to active metabolites. The active metabolites are excreted in the urine and feces. The pharmacokinetics of sumatriptan are affected by age, sex, and body weight.

**DIAGNOSIS**
To diagnose migraine headache, a healthcare provider should make together, taking into account your personal needs and medical history. They may ask questions about your symptoms and do physical and/or neurological examinations to rule out other conditions that can mimic migraine.

**PROPHYLACTIC MEDICATIONS**
In patients taking MAO-A inhibitors, sumatriptan plasma levels attained after treatment are more than 10 times higher than those following the use of sumatriptan tablets. Similarly, in patients taking ergotamine, dihydroergotamine, or methysergide, sumatriptan plasma levels are more than 20 times higher than those following the use of sumatriptan tablets. Patients should be monitored for signs of serotonin syndrome, including agitation, anxiety, confusion, diaphoresis, nausea, vomiting, diarrhea, myoclonus, tremor, and hypotension.

**PATIENT INFORMATION**
Patients should be advised to read the Patient Information Leaflet before starting treatment with sumatriptan succinate injection. They should also be advised to report any adverse reactions to their healthcare provider.

**REFERENCES**
Based on clinical trial data and the results of the analysis of adverse event data from postmarketing surveillance and case reports. The efficacy and safety of sumatriptan succinate injection were also evaluated in a systematic review of published data, which included over 1,000 patients with migraine headaches.
The Use of Sumatriptan Succinate Injection During Pregnancy:

How to store your medicine:

There is no evidence that establishes that sumatriptan is a human teratogen; however, there are no adequate and well-controlled studies in pregnant women. Therefore, if you are pregnant, are trying to become pregnant, or are not using adequate contraception, do not use sumatriptan succinate injection. If you do have a migraine attack while you are pregnant, are trying to become pregnant, or are not using adequate contraception, tell your healthcare provider before you use sumatriptan succinate injection. If you get pregnant while using sumatriptan succinate injection, tell your healthcare provider.

Provider information:

The studies did not establish the efficacy of sumatriptan nasal spray, subcutaneous sumatriptan daily prior to and throughout pregnancy, there was no evidence for serious adverse events in pediatric patients who might receive injectable, oral, or intranasal sumatriptan. In placebo-controlled trials in adult and pediatric patients treated a single attack. The studies did not establish the efficacy of sumatriptan nasal spray, subcutaneous sumatriptan daily prior to and throughout pregnancy, there was no evidence for serious adverse events in pediatric patients who might receive injectable, oral, or intranasal sumatriptan.

Use in migraine:

Some possible side effects of sumatriptan succinate injection include:

- Headache, nausea, vomiting, dizziness, flushing, or swelling
- Blurred vision, drowsy, dizzy, tired, or sick
- Feelings of warmth, coldness, or itching
- Feeling strange
- Weakness
- Pallor
- Swollen or painful joints
- Bone pain
- Atypical sensations

If you have any of these symptoms, stop taking sumatriptan succinate injection and talk to your healthcare provider before you use more sumatriptan succinate injection.

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Prozac, Sarafem Capsules, Symbyax, and Cymbalta are registered trademarks of Eli Lilly and Company.

Non-Serotoninergic Antidepressants

Some possible side effects of sumatriptan succinate injection include:

- Headache, nausea, vomiting, dizziness, flushing, or swelling
- Blurred vision, drowsy, dizzy, tired, or sick
- Feelings of warmth, coldness, or itching
- Feeling strange
- Weakness
- Pallor
- Swollen or painful joints
- Bone pain
- Atypical sensations

If you have any of these symptoms, stop taking sumatriptan succinate injection and talk to your healthcare provider before you use more sumatriptan succinate injection.

Keep the leaflet for reference because it gives you a summary of important information to discuss with your healthcare provider before taking sumatriptan succinate injection.

Table 4. Treatment-Emergent Adverse Experience Incidence in 2 Large Placebo-Controlled Studies

<table>
<thead>
<tr>
<th>Experience</th>
<th>Placebo (n=370)</th>
<th>Placebo (n=370)</th>
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<tbody>
<tr>
<td>Atypical sensations</td>
<td>42</td>
<td>9</td>
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<tr>
<td>Feeling strange</td>
<td>&lt;1</td>
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<tr>
<td>Weakness</td>
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<tr>
<td>Pallor</td>
<td>23</td>
<td>15</td>
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<tr>
<td>Swollen or painful joints</td>
<td>12</td>
<td>7</td>
</tr>
<tr>
<td>Bone pain</td>
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<td>7</td>
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The list of adverse events in the table above may not be a complete list of all possible adverse events. Some adverse events may be more common in certain groups of patients. It is important to discuss these events with your healthcare provider before taking sumatriptan succinate injection.

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Prozac, Sarafem Capsules, Symbyax, and Cymbalta are registered trademarks of Eli Lilly and Company.

Information for the Patient

Sumatriptan Succinate Injection

Do not use sumatriptan succinate injection if you have:

- Ever had heart disease, except migraines treated with subcutaneous sumatriptan injection two times a day prior to and throughout pregnancy, there was no evidence for serious adverse events in pediatric patients who might receive injectable, oral, or intranasal sumatriptan.

If you do have risk factors for heart disease, your healthcare provider should check you for heart disease to see if sumatriptan succinate injection is right for you.

Before you use sumatriptan succinate injection, tell your healthcare provider if you have risk factors for heart disease such as:

- Strong family history of heart disease,
- Strong family history of stroke,
- History of heart attack or heart disease or stroke,
- High blood pressure,
- High cholesterol,
- Coronary artery disease,
- Diabetes,
- Asthma,
- Pulmonary embolism,
- Varicose veins,
- Pregnancy or breastfeeding,
- Surgery or severe illness during the last 6 months,
- Severe migraine that has happened in the last 3 months,
- Coronary artery disease,
- Stroke,
- High cholesterol or triglycerides,
- High blood pressure,
- High blood sugar,
- Diabetes,
- Heart attack,
- Angina,
- Asthma,
- Pulmonary embolism,
- Varicose veins,
- Surgery or severe illness during the last 6 months,
- Severe migraine that has happened in the last 3 months,
- Coronary artery disease,
- Stroke,
- High cholesterol or triglycerides,
Each 0.5 mL of solution contains 4 mg of sumatriptan (as the succinate salt) and 3.8 mg of sodium chloride.

Sterile, nonpyrogenic.

Usual Dosage: See package insert.

Store at 20°-25°C (68°-77°F) (see USP Controlled Room Temperature). Protect from light.

RETAIN IN CARTON UNTIL TIME OF USE. KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
<table>
<thead>
<tr>
<th>WIDTH (INCH)</th>
<th>HEIGHT (INCH)</th>
<th>CORNER RADIUS (INCH)</th>
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</tbody>
</table>

RSS: 1030781323147 6
**Sumatriptan Succinate Injection**

**INDICATIONS AND USAGE**

Sumatriptan succinate injection is indicated for 1) the acute treatment of migraine headache (with or without aura) when used according to the recommended dosing schedule. It is not indicated for the prevention of migraine headache.

**CONTRAINDICATIONS**

Sumatriptan succinate injection is contraindicated in patients with: 1) a history of sensitization to sumatriptan or any of its components, 2) uncontrolled hypertension, 3) cerebrovascular disease, 4) uncontrolled cardiovascular disease, 5) peripheral vascular disease, and 6) a history of coronary artery disease.

**WARNINGS**

- **Heart Disease:** Among approximately 4,000 patients with migraine who participated in premarket clinical trials of sumatriptan succinate injection, 247 (6%) had cardiovascular disease. During postmarketing surveillance, 467 cases of coronary artery disease (myocardial infarction, angina, coronary artery bypass graft, coronary angioplasty) were reported with sumatriptan succinate injection.
What to do if you take an overdose:

How to Use Sumatriptan Succinate Injection:

1. Some patients feel pain or tightness in the chest or throat when using sumatriptan succinate injection. If this happens to you, then discuss it with your healthcare provider.

2. Some people may have a reaction called serotonin syndrome when they use certain types of antidepressants, SSRIs or SNRIs, while taking sumatriptan succinate injection. If you have taken more medicine than has been prescribed for you, contact either your healthcare provider, hospital emergency department, or nearest poison control center immediately.

Remember, if you answered ‘yes’ to any of the above questions, then talk to your healthcare provider before taking sumatriptan succinate injection. Do not store at temperatures above 86°F (30°C).

WARNINGS: Concomitant Drug Use

A fertility study (Segment I) by the subcutaneous route, during which male and female patients were treated with sumatriptan daily prior to and throughout pregnancy, there was no evidence of increased risk of congenital malformations among infants born to women treated with sumatriptan daily. However, the number of patients in this study was small. At present, there are no adequate and well-controlled studies in pregnant women. Therefore, sumatriptan succinate injection should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

If your healthcare provider decides to stop your treatment, do not keep any leftover sumatriptan succinate injection. If you have taken more medicine than has been prescribed for you, contact either your healthcare provider, hospital emergency department, or nearest poison control center immediately.

Serious cardiac events, including some that have been fatal, have occurred following the sumatriptan nasal spray use. It is unknown whether the same events have occurred following the sumatriptan succinate injection use are likely to be similar regardless of route of administration.

Important Questions to Consider Before Taking Sumatriptan Succinate Injection:

1. Are you allergic to sumatriptan succinate injection or any other component in this product?

2. Is your age younger than 18 years?

3. Are you pregnant? Do you think you might be pregnant? Are you trying to become pregnant, or are you not using adequate contraception?

4. Do you have a heart condition?

5. Do you have high blood pressure?

6. Do you have liver or kidney disease?

7. Do you have a history of peptic ulcer disease?

8. Do you have a bleeding disorder?

9. Do you have Raynaud’s disease?

10. Do you have a history of heart attack or stroke?

11. Do you have a history of a heart rhythm disorder?

12. Do you have Raynaud’s disease?

13. Do you smoke or are you a former smoker?

14. Do you have a personal or family history of depression?

15. Do you have a personal or family history of a neurological disorder?

16. Do you have a history of migraine with Aura?

17. Do you have a personal or family history of suicidal thoughts or attempts?

18. Do you have a personal or family history of serotonin syndrome?

19. Do you have a personal or family history of a 5-HT1A receptor agonist-induced (morphine, methadone, tramadol, etc.) syndrome?

20. Do you have a history of alcoholism, drug abuse, or drug dependence?

21. Do you have a personal or family history of HLA-B*5701 allele?

22. Do you have a history of sleep apnea?

23. Do you have a history of cancer?

24. Do you have a history of peripheral neuropathy?

25. Do you have a history of bladder irritation?

26. Do you have a history of anaphylaxis?

27. Do you have a history of interstitial lung disease?

28. Do you have a history of HLA-B*5701 allele?

29. Do you have a history of diabetes mellitus?

30. Do you have a history of hepatic impairment, including fulminant hepatic failure?

31. Do you have a history of renal impairment?

32. Do you have a history of peripheral neuropathy?

33. Do you have a history of Raynaud’s phenome

Other Events Observed in the Clinical Development of Sumatriptan Succinate:

Neurological:

- Abnormal gait
- Headache
- Infarction
- Memory disturbance
- Numbness

Pain and Other Pressure Sensations:

- Abdominal pain
- Chest pain
- Jaw pain
- Muscular pain

Cardiovascular:

- Anaphylaxis
- Cardiac arrhythmia
- Chest pain
- Coronary artery spasm
- Increased blood pressure
- Palpitations

Exacerbation of sunburn, hypersensitivity reactions (allergic vasculitis, erythema, rash, angioedema), and vasculitis.

Pregnancy:

No adequate and well-controlled studies in pregnant women. Therefore, sumatriptan succinate injection should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

If you have taken more medicine than has been prescribed for you, contact either your healthcare provider, hospital emergency department, or nearest poison control center immediately.

If you have taken more medicine than has been prescribed for you, contact either your healthcare provider, hospital emergency department, or nearest poison control center immediately.

Keep your medicine in a safe place where children cannot reach it. It may be harmful to children.

Store your medicine away from heat and light. Keep your medicine in the packaging provided. Do not store at temperatures above 86°F (30°C).
Sumatriptan Succinate Injection
FOR SUBCUTANEOUS INJECTION ONLY
Sterile. Discard unused portion.

6 mg/0.5 mL*
5 x 0.5 mL Single-Dose Vials
NDC 0781-3230-14

*Each 0.5 mL of solution contains 6 mg of sumatriptan (as the succinate salt) and 3.5 mg of sodium chloride
Sterile, nonpyrogenic
Usual Dosage: See package insert
Store at 20°-25°C (68°-77°F) (see USP Controlled Room Temperature)
Protect from light: RETAIN IN CARTON UNTIL TIME OF USE. KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
09-2008M
Manufactured in Canada by Sandoz Canada Inc for Sandoz Inc, Princeton, NJ 08540

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