

PATIENT INFORMATION

Sumatriptan Injection, USP (sue-muh-TRIP-tan)



What is the most important information I should know about sumatriptan injection?

Sumatriptan injection can cause serious side effects, including:

Heart attack and other heart problems. Heart problems may lead to death.

Stop taking sumatriptan 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 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
- smoke
- are overweight
- have diabetes
- have a family history of heart disease

What is sumatriptan injection?

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

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

Do not take sumatriptan 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 (RELPA[®])
 - 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 injection. See the end of this leaflet for a complete list of ingredients in sumatriptan injection.

Before taking sumatriptan 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
- are allergic to latex
- have had epilepsy or seizures
- are not using effective birth control
- are pregnant or plan to become pregnant. It is not known if sumatriptan injection can harm your unborn baby.
- are breastfeeding or plan to breastfeed. Sumatriptan passes into your breast milk.
- It is not known if this can harm your baby. Talk with your healthcare provider about the best way to feed your baby if you take sumatriptan injection.

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

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

Especially tell your healthcare provider if you take antidepressant 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 injection?

- Certain people should take their first dose of sumatriptan 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 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, 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 injection so you can talk with your healthcare provider about how sumatriptan injection is working for you.

What should I avoid while taking sumatriptan injection?

Sumatriptan 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 injection?

Sumatriptan injection may cause serious side effects. See "What is the most important information I should know about sumatriptan 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
- medication overuse headaches. Some people who use too many sumatriptan injections may have worse headaches (medication overuse headache). If your headaches get worse, your healthcare provider may decide to stop your treatment with sumatriptan injection.
- serotonin syndrome. Serotonin syndrome is a rare but serious problem that can happen in people using sumatriptan injection, especially if sumatriptan 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
- hives (itchy bumps); swelling of your tongue, mouth or throat.

- seizures. Seizures have happened in people taking sumatriptan injection who have never had seizures before. Talk with your healthcare provider about your chance of having seizures while you take sumatriptan injection.

The most common side effects of sumatriptan 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 injection.

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 injection?

- Store sumatriptan injection at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F).
- Store your medicine away from light.
- Keep your medicine in the packaging provided with it.

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

General information about the safe and effective use of sumatriptan injection

Medicines are sometimes prescribed for purposes other than those listed in Patient Information leaflets. Do not use sumatriptan injection for a condition for which it was not prescribed. Do not give sumatriptan 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 injection. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about sumatriptan injection that is written for healthcare professionals.

For more information, call 1-800-818-4555.

What are the ingredients in sumatriptan 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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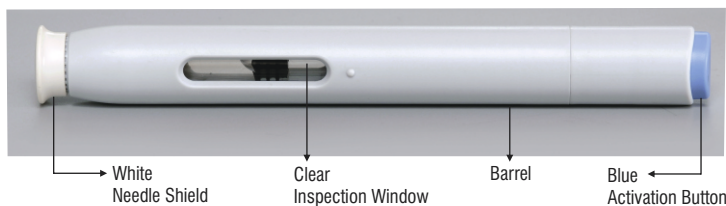
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HOW TO USE Autoinjector for Sumatriptan Injection, USP 6 mg/0.5 mL

Figure 1 (frontal view of autoinjector)



This leaflet explains how to use the sumatriptan autoinjector. Read it **TWICE** before you begin the first step. If you have any questions, ask your doctor or pharmacist. For use only patients for whom a 6 mg dose has been prescribed.

CAUTIONS:

- Check** the expiration date on the autoinjector label.
- Keep** the autoinjector in its box until you are ready to use it.
- Keep** the sumatriptan injection autoinjector out of the reach of children.
- Do not** remove the white needle shield from the autoinjector until you are ready to inject.
- NEVER** put the white needle shield back into the autoinjector after injection.
- NEVER** put or press thumb, fingers, or hand over white needle cover.
- Check** the appearance of sumatriptan injection, through the inspection window. It must be a clear, colorless to pale yellow solution. Do not inject the solution if it looks discolored or cloudy or contains lumps, flakes, or particles. The needle shield of the prefilled syringe contains dry natural rubber, which is made from latex. This is a part you cannot usually see, but it could still cause an allergic reaction. Tell your healthcare provider if you are allergic to latex.
- Before** you use sumatriptan injection autoinjector your healthcare provider should show you or your caregiver how to give an injection the right way.
- Be** sure to change the injection site with each dose.

HOW TO USE THE AUTOINJECTOR

Wash your hands thoroughly.

Find a comfortable, well-lit place and put everything you need where you can reach it (autoinjector, alcohol or sterile swabs).

Identify the application area with an adequate fatty tissue layer on top part of the thigh or back of the arm. Do not inject into areas where the skin is tender, bruised, red, or hard.

Wipe the injection site with alcohol or a new sterile swab and allow your skin to dry. Do not touch this area again before giving the injection.

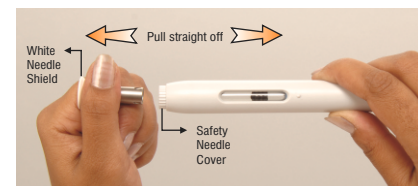
Take out the injector from show box.

Figure 2



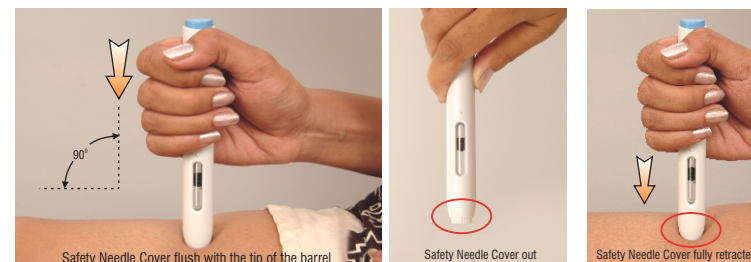
Pick up the autoinjector in one hand and smoothly remove the white needle shield by pulling it straight off. Do not twist it off, and do not recap the white needle shield, as either of these may damage the needle inside the autoinjector. The autoinjector has a cover that will protect you from needle sticks or loss of drug by accidental bumping or touching (See Figure 3).

Figure 3



Without pressing the blue activation button, place the open end of the autoinjector on the injection site, straight up at a right angle (90°) and push the safety needle cover firmly against the skin to unlock. **Continue to hold firmly against the skin** (See Figure 4).

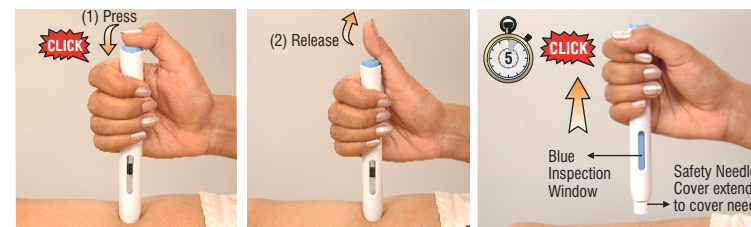
Figure 4



To start the injection (1) Press the Blue Button (first click will sound), (2) immediately release your thumb. This starts the injection. Do not lift the autoinjector off the skin. Wait until you hear the second 'click'. Once you hear the second click, lift the autoinjector straight up from the injection site. The injection is finished. The safety needle cover on the autoinjector will automatically extend to cover the needle. The needle will not be visible now.

If you did not remove your thumb from the blue button, the second 'click' cannot be heard. If this happens, slowly count to 5 before lifting the autoinjector from the injection site. The inspection window will be blue, confirming the injection is complete. Verify that the inspection window is blue to ensure that the injection is complete before lifting the autoinjector (See Figure 5).

Figure 5



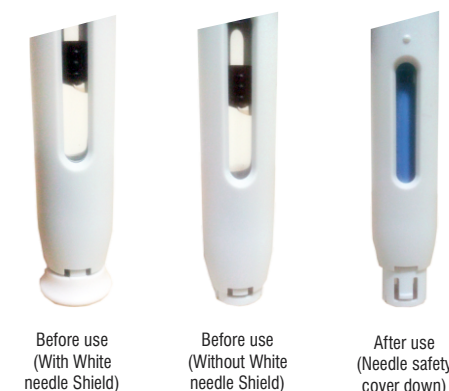
The needle safety cover will move down over the needle and lock into place. There is no need to replace the white needle shield.

If the inspection window is not blue, do not try to use the autoinjector again.

If you suspect you have not received the full dose, do not repeat the injection using a new autoinjector.

If you notice a spot of blood at the injection site, dab away with a cotton ball or tissues. Do not rub the injection site. If needed, you may cover the injection site with a bandage.

Figure 6



Discard sumatriptan injection autoinjector after use. **NEVER ATTEMPT TO REUSE AN AUTOINJECTOR**