



PATIENT INFORMATION
Sumatriptan Injection USP
(soo" ma trip' tan)

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

Sumatriptan can cause serious side effects, including:

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

Stop taking sumatriptan 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?

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

It is not known if sumatriptan 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:
 - o almotriptan (AXERT)
 - o frovatriptan (FROVA)
 - o rizatriptan (MAXALT, MAXALT-MLT)
 - o eletriptan (RELPAK)
 - o naratriptan (AMERGE)
 - o sumatriptan and naproxen (TREMEX)
 - o dihydroergotamine (D.H.E. 45, MIGRANAL)
 - o ergotamines (CAFERGOT, ERGOMAR, o MIGERGOT)

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
- have had epilepsy or seizures
- are not using effective birth control
- become pregnant while taking sumatriptan
- are pregnant or plan to become pregnant. It is not known if sumatriptan 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.

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

Sumatriptan 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 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 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 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 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:
 - o sudden or severe stomach pain
 - o stomach pain after meals
 - o weight loss
 - o fever
 - o nausea or vomiting
 - o constipation or diarrhea
 - o bloody diarrhea
- problems with blood circulation to your legs and feet (peripheral vascular ischemia). Symptoms of peripheral vascular ischemia include:
 - o cramping and pain in your legs or hips
 - o feeling of heaviness or tightness in your leg muscles
 - o burning or aching pain in your feet or toes while resting
 - o numbness, tingling, or weakness in your legs
 - o 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.
- 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 antidepressant 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 at 25°C (77°F); excursions permitted 15°C to 30°C (59°F to 86°F)
- Store your medicine away from light.
- Keep your medicine in the packaging or carrying case 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 1-888-375-3784.

What are the ingredients in sumatriptan injection?

Active ingredient: sumatriptan succinate USP

Inactive ingredients: sodium chloride, water for injection

The other brands listed are trademarks of their respective owners and are not trademarks of Dr. Reddy's Laboratories Limited. The makers of these brands are not affiliated with and do not endorse Dr. Reddy's Laboratories Limited or its products.

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

SUMATRIPTAN INJECTION

INSTRUCTIONS FOR USE OF DISPOSABLE SUMATRIPTAN AUTOINJECTOR SYSTEM

Read this Patient Instructions for Use before you start to use Sumatriptan Autoinjector System. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment. You and your healthcare provider should talk about sumatriptan injection when you start taking it and at regular checkups.



- Use the device immediately once the cap has been removed; it is advised not to postpone the injection.
- Keep the Sumatriptan Autoinjector System out of the reach of children.

INSTRUCTIONS FOR USE OF AUTOINJECTOR PEN

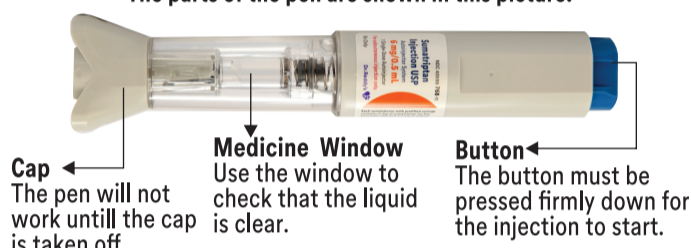
Important things that you need to know

This device is called an Autoinjector pen. Here we use the shorter name 'pen'.

1. Read all of the instructions carefully before using this pen.
2. Follow these step-by-step instructions every time you use the pen, ask your doctor or pharmacist.
3. Only use each pen once - do not try to use more than once. If you have any further questions.

A. ABOUT THE AUTOINJECTOR PEN

The parts of the pen are shown in this picture.



B. GETTING READY

Getting ready for the injection.

1. Wash your hands.
2. Choose an area with an adequate fatty tissue layer.
3. Clean the skin area to be injected with alcohol or a new sterile swab (see Figure A).

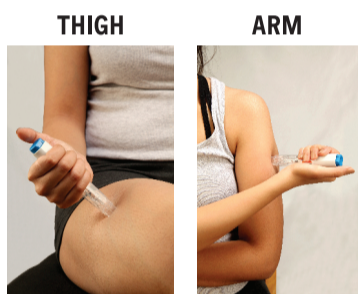


Figure A

Getting the pen ready.

4. Take the pen out of the package.
5. Look in the transparent medicine window on the pen.
 - Before injection, to check that the liquid is clear (see Figure B).
 - If it is difficult to see what is in the window, hold the pen up to the light and check.
 - After injection, the blue plunger rod completely fills the medicine window (see Figure C).
 - If the blue plunger rod can be seen through the medicine window, the device is spent and cannot be used again.

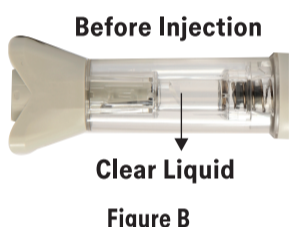


Figure B

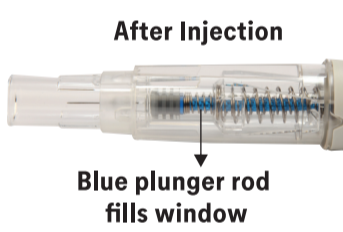


Figure C

6. Pull the gray cap off the pen.

- Do not twist the cap.
- Pull it straight off (see Figure D).



Figure D

7. Look inside the cap, check that the gray needle cover is inside (see Figure E).

- Do not use the pen if the gray needle cover is not inside the cap.

8. Do not try to put the cap back

If you try to put it back, this will damage the needle.

You are now ready to inject the medicine, go to step 9.



Figure E

C. INJECTING THE MEDICINE

9. Without pressing the blue button, push the pen firmly against your skin until you feel the stop point (see Figure F).

- Pushing to the stop point unlocks the button.
- As long as the pen is firmly pressed against the skin, the safety lock is deactivated; the pen could fire unintentionally if the blue button is pressed by accident.
- Do not attempt to re-engage the safety lock at any time.
- Keep the pen pressed against your skin for the next steps.

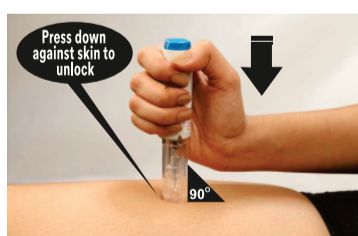


Figure F

10. Keep pushing the pen against your skin then firmly press down the blue button on the top of the pen until it will not go further (see Figure G).

- You will hear a click, this indicates that the injection has started (see Figure G).
- If the injection did not start, release the blue button, make sure the pen is pushed down against the skin and push down harder on the blue button.



Figure G

11. Do not take the pen off your skin.

- Monitor the injection through the medicine window to make sure that the entire dose is injected. The blue plunger will move down the window, completely fill it, and stop moving when the injection is done (see Figure H).
- When the injection is done, keep holding the pen against the skin for 5 seconds (see Figure I). If you take the pen off before, not all of the medicine will be injected.



Figure H

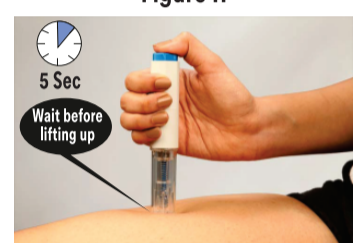


Figure I

12. Carefully take the pen off your skin (see Figure J).

- The protective sleeve automatically covers the needle. It is then locked and the needle is protected.



Figure J

D. WHAT TO DO AFTER THE INJECTION

13. If you notice a spot of blood at the injection site, dab away with a cotton ball or tissue paper. Do not rub the injection site. If needed, you may cover the injection site with a bandage.
14. Visually check that there is no liquid left at the bottom of the medicine window. If there is liquid, consult your doctor or pharmacist.

E. DISPOSE THE AUTOINJECTOR PEN

15. Discard the whole sumatriptan injection pen after use and discard the cap.

- Put your used injection pen in a FDA-cleared sharps disposal container right away after use (see Figure K).



Figure K

• If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:

- o made of a heavy-duty plastic,
- o can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out, upright and stable during use,
- o leak-resistant, and
- o properly labeled to warn of hazardous waste inside the container.

- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and cartridges. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

- Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

Do not try to reuse the autoinjector pen. To avoid any injury, never try to touch the needle.

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

To reorder additional Patient information sheets contact Dr. Reddy's Customer Service at 1-866-733-3952.

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