

Sumatriptan Injection USP

Autoinjector System

6 mg/0.5 mL

For Subcutaneous Use



Rx Only

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

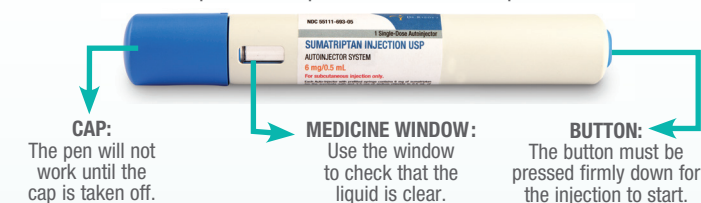
Important things that you need to know

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.
3. Only use each pen once – do not try to use more than once. If you have any further questions, ask your doctor or pharmacist.

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.



THIGH

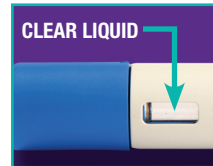


ARM

Getting the pen ready

4. Take the pen out of the package.
5. Look in the medicine window on the pen.
 - Before injection, to check that the liquid is clear.
 - If it is difficult to see what is in the window, hold the pen up to the light and check.
 - After injection, the plunger rod completely fills the medicine window.

BEFORE INJECTION:



AFTER INJECTION:



If the plunger rod can be seen through the medicine window, the device is spent and cannot be used again.

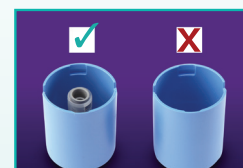
6. Pull the cap off the pen.

- Do not twist the cap.
- Pull it straight off.
- Keep the cap for step 7.



7. Look inside the cap, check that the gray needle cover is inside.

- 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.

(Continued on other side)

INDICATION

Sumatriptan Injection USP is a prescription medicine used to treat acute migraine headaches with or without aura and acute cluster headaches in adults.

IMPORTANT SAFETY INFORMATION

- Sumatriptan can cause serious side effects such as death, heart attack, stroke, increased high blood pressure, fast heartbeat, changes in mental status like hallucination, agitation and coma, tight muscles or trouble walking, changes in the color or feelings of fingers or toes, decreased blood flow to arms, legs or intestines.
- Do not take sumatriptan if you have heart disease or a history of heart disease, narrowing of blood vessels in the arms, legs, stomach or kidney, uncontrolled high blood pressure, migraines that cause temporary paralysis on one side of the body or Basilar migraine, had a stroke or transient ischemic attack or other issues with blood circulation.
- Do not take sumatriptan if you have taken another triptan or ergotamine medication in the last 24 hours or are allergic to sumatriptan or its ingredients.

Please see additional Important Safety Information on the back.

Please see accompanying full Prescribing Information and Patient Information.

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(Continued from previous side)

C. INJECTING THE MEDICINE

9. Without pressing the blue button, push the pen firmly against your skin.

- You will now see a small blue projection in the medicine window.
- As long as the blue circle is visible in the medicine window, the safety lock is de-activated; the pen could fire unintentionally if the blue button is pressed by accident.



Keep the pen pressed against your skin for the next steps.

10. Do not attempt to re-engage the safety lock at any time.

11. Firmly press down the blue button on the top of the pen until it will not go further.

- You will hear a loud click (this indicates that the injection has started).
- Keep pushing the pen against your skin.



12. Do not take the pen off your skin.

- Wait for about 5 seconds until you hear the second click.
- The second click indicates you that the injection has finished.
- If you take the pen off before the second click, not all the medicine will be injected.

13. Carefully take the pen off your skin.



D. WHAT TO DO AFTER THE INJECTION

14. Replace the cap right away



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.

15. Discard the whole sumatriptan injection autoinjector after use. Do not try to reuse the autoinjector pen.

IMPORTANT SAFETY INFORMATION (Continued from previous side)

- 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)
- 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.

INDICATION

Sumatriptan Injection USP is a prescription medicine used to treat acute migraine headaches with or without aura and acute cluster headaches in adults.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see accompanying full Prescribing Information, Patient Information, Instructions for Use, web site and Self-Administration video at www.drreddys.com/products/NA/Sumatriptan.html.

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For more information,
contact Medical Information
at 888-375-3784 or
visit our Web site using
the code provided.

