



# Information for the Patient Sumatriptan Succinate Injection

See the other side for “Instructions for Use” for Autoinjector.

Read this leaflet carefully before you start to take sumatriptan succinate injection. Keep the leaflet for reference because it gives you a summary of important information about sumatriptan succinate injection.

Read the leaflet that comes with each refill of your prescription because there may be new information. This leaflet does not have all the information about sumatriptan succinate injection. Ask your healthcare provider for more information or advice.

### What is sumatriptan succinate injection?

Sumatriptan succinate injection is a 5-HT<sub>1</sub> agonist. It is also called a “triptan.” You should use it only if you have a prescription.

Sumatriptan succinate injection is used to relieve your migraine or cluster headache. Sumatriptan succinate injection is not used to prevent attacks or reduce the number of attacks you have. Use sumatriptan succinate injection only to treat an actual migraine or cluster headache attack.

The decision to use sumatriptan succinate injection is one that you and your healthcare provider should make together, taking into account your personal needs and health.

### Talk to your healthcare provider before taking sumatriptan succinate injection

#### 1. Risk factors for heart disease:

Tell your healthcare provider if you have risk factors for heart disease such as:

- high blood pressure,
- high cholesterol,
- obesity,
- diabetes,
- smoking,
- strong family history of heart disease,
- you are postmenopausal, or
- you are a male over 40 years of age.

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.

Although most of the people who have taken sumatriptan succinate injection have not had any serious side effects, some have had serious heart problems. Deaths have been reported, but these were rare considering the extensive worldwide use of sumatriptan succinate injection. Usually, serious problems happened in people with known heart diseases. It was not clear whether sumatriptan succinate injection had anything to do with these deaths.

#### 2. Important questions to consider before taking sumatriptan succinate injection:

If the answer to any of the following questions is **YES** or if you do not know the answer, then please talk with your healthcare provider before you use sumatriptan succinate injection.

- Are you pregnant? Do you think you might be pregnant? Are you trying to become pregnant? Are you using inadequate contraception? Are you breastfeeding?

- Do you have any chest pain, heart disease, shortness of breath, or irregular heartbeats? Have you had a heart attack?
- Do you have risk factors for heart disease (such as high blood pressure, high cholesterol, obesity, diabetes, smoking, strong family history of heart disease, or you are postmenopausal or a male over 40)?
- Have you had a stroke, transient ischemic attacks (TIAs), or Raynaud syndrome?
- Do you have high blood pressure?
- Have you ever had to stop taking this or any other medicine because of an allergy or other problems?
- Are you taking any other migraine medicines, including other 5 HT<sub>1</sub> agonists (triptans) or any other medicines containing ergotamine, dihydroergotamine, or methysergide?
- Are you taking any medicine for depression or other disorders such as monoamine oxidase inhibitors, selective serotonin reuptake inhibitors (SSRIs), or serotonin norepinephrine reuptake inhibitors (SNRIs)? Common SSRIs are citalopram HBr (CELEXA<sup>®</sup>\*), escitalopram oxalate (LEXAPRO<sup>®</sup>\*), paroxetine (PAXIL<sup>®</sup>\*), fluoxetine (PROZAC<sup>®</sup>\*/SARAFEM<sup>®</sup>\*), olanzapine/fluoxetine (SYMBYAX<sup>®</sup>\*), sertraline (ZOLOFT<sup>®</sup>\*), and fluvoxamine. Common SNRIs are duloxetine (CYMBALTA<sup>®</sup>\*) and venlafaxine (EFFEXOR<sup>®</sup>\*).
- Have you had, or do you have, any disease of the liver or kidney?
- Have you had, or do you have, epilepsy or seizures?
- Is this headache different from your usual migraine attacks?

Remember, if you answered **YES** to any of the above questions, then talk with your healthcare provider about it.

### Important points about sumatriptan succinate injection

#### 1. The use of sumatriptan succinate injection during pregnancy:

Do not use sumatriptan succinate injection if you are pregnant, think you might be pregnant, are trying to become pregnant, or are not using adequate contraception unless you have talked with your healthcare provider about this.

#### 2. How to use sumatriptan succinate injection:

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 migraine start, but it may be given at any time during an attack. You may give a second injection if your migraine symptoms come back. If your symptoms do not get better after the first injection, do not give a second injection for the same attack without first talking with your healthcare provider. Do not give more than two 6 mg doses in any 24-hour period. Allow at least 1 hour between each dose.

#### 3. What to do if you take an overdose:

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.

#### 4. How to store your medicine:

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 77°F (25°C). The expiration date of your medicine is printed on both autoinjector and prefilled single-dose syringe. If your medicine has expired, throw it away as instructed. If your healthcare provider decides to stop your treatment, do not keep any leftover medicine unless your healthcare provider tells you to. Throw away your medicine as instructed.

### Some possible side effects of 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 before using any more sumatriptan succinate injection. If the chest pain is severe or does not go away, call your healthcare provider right away.
2. Call your healthcare provider right away if you have sudden and/or severe abdominal pain following sumatriptan succinate injection.
3. Some people may have a reaction called serotonin syndrome when they use certain types of antidepressants, SSRIs or SNRIs, while taking sumatriptan succinate injection. Symptoms may include confusion, hallucinations, fast heartbeat, feeling faint, fever, sweating, muscle spasm, difficulty walking, and/or diarrhea. Call your doctor immediately if you have any of these symptoms after taking sumatriptan succinate injection.
4. Shortness of breath; wheeziness; heart throbbing; swelling of eyelids, face, or lips; or a skin rash, skin lumps, or hives happens rarely. If it happens to you, then tell your healthcare provider right away. Do not take any more sumatriptan succinate injection unless your healthcare provider tells you to.
5. Some people may feel tingling, heat, flushing (redness of face lasting a short time), heaviness, or pressure after using sumatriptan succinate injection. A few people may feel drowsy, dizzy, tired, or sick. If you have any of these symptoms, tell your healthcare provider at your next visit.
6. You may have pain or redness at the site of injection, but this usually lasts less than an hour.
7. If you feel unwell in any other way or have any symptoms that you do not understand, you should contact your healthcare provider right away.

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## HOW TO USE Autoinjector for Sumatriptan Succinate Injection, 6 mg/0.5 mL

Figure 1 (frontal view of autoinjector)



This leaflet explains how to use the sumatriptan succinate 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 succinate 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 succinate 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.

### 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. Make sure the skin under and around the prefilled autoinjector is firm and taut to provide enough resistance to fully retract the safety guard and unlock the prefilled autoinjector (See Figure 2).

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