



Zembrace[®] SYMTOUCH[®]
(sumatriptan injection) 3 mg



**Get migraine
pain relief—fast^{1,2}**

Zembrace[®] SymTouch[®] is a prescription medicine used to treat acute migraine headaches with or without aura in adults 18 years of age and older who have been diagnosed with migraine.

Zembrace[®] SymTouch[®] is not used to prevent or decrease the number of migraines you have.

Do not take Zembrace[®] SymTouch[®] if you have hemiplegic migraines or basilar migraines. This is not the only reason not to take Zembrace[®] SymTouch[®]. If you are not sure if you have these types of migraines, ask your healthcare provider.

Please see Important Safety Information on pages 12 to 15 and full Prescribing Information, including Patient Information and Instructions for Use at [Zembrace.com](https://www.zembrace.com).



Migraine is a neurological condition

A migraine can cause severe pain, pulsing or throbbing in the head that can last from a few hours to a few days if untreated. This—in addition to symptoms other than pain—makes migraine distinct from just a bad headache:

- **Migraines can occur with varying frequency**—from only rarely to many days each month. For some people, the symptoms can be so disabling that it disrupts their personal, family and work life.
- **Migraine symptoms vary from person to person** and can include intense pain; pain on one side of the head; nausea or vomiting; extreme sensitivity to light, noise or smells; blurred vision and dizziness. Some patients may experience an “aura” before migraine.



What is Zembrace[®] SymTouch[®]

Zembrace[®] SymTouch[®] is a prescription medicine used to treat acute migraine headaches with or without aura in adults 18 years of age and older who have been diagnosed with migraine.

How can Zembrace[®] SymTouch[®] help

Zembrace[®] SymTouch[®] is a ready-to-use, single-use pen (auto-injector) containing 3 mg of sumatriptan. 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 headache attack.

Do not use Zembrace[®] SymTouch[®] if you have: heart problems or a history of heart problems; had a stroke, transient ischemic attacks (TIAs), or problems with your blood circulation. These are not all of the reasons you should not use Zembrace[®] SymTouch[®].

Please see Important Safety Information on pages 12 to 15 and full Prescribing Information, including Patient Information and Instructions for Use at Zembrace.com.

When timing is everything

You want migraine pain relief—fast.^{1,2}
Zembrace[®] SymTouch[®] may help you return
to the moments that matter most.

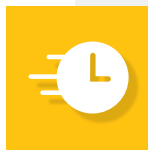


If you suffer from any of the following migraines,
Zembrace[®] SymTouch[®] may be able to help:



Morning migraine

Nearly half of all migraine attacks
occur between 4 and 9 a.m.³



Rapid-onset migraine

A migraine that reaches full
force quickly.



Migraine with nausea

73% of patients with migraine
have experienced nausea
(with or without vomiting) during
migraine attacks.⁴

**Zembrace[®] SymTouch[®] is indicated for the
acute treatment of migraine with or without
aura in adults.**

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including Patient Information and Instructions
for Use at Zembrace.com.**



Fast and powerful^{1,2}

In as little as 10 minutes, you may get migraine pain relief (17% of patients for sumatriptan 3 mg vs. 5% for placebo).[†] One study showed that 60% of people experienced pain relief within 2 hours of use (vs. 21% for placebo).¹

[†]Time to onset and degree of pain relief varies by patient.

The most common side effects of Zembrace[®] SymTouch[®] include pain and 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.

Simple to use

Zembrace[®] SymTouch[®] is a convenient, ready-to-use pen:

- Smallest needle in a sumatriptan pen⁵
- Simple two-step injection process^{1,6}
- Do not refrigerate[‡]

[‡]Store between 68°F and 77°F. Excursions permitted between 59°F and 86°F.

Please see Important Safety Information on pages 12 to 15 and full Prescribing Information, including Patient Information and Instructions for Use at Zembrace.com.

Two-step injection process

See accompanying full
Instructions for Use.

1 Remove protective cap.

Before administering, be sure that the injection site is properly cleaned. Ensure that the used pen is properly disposed of immediately after use.



2 Push against clean injection site and hold until you hear the device click.



Wait 5 seconds after second click before removing.

Please see Important Safety Information on pages 12 to 15 and full Prescribing Information, including Patient Information and Instructions for Use at Zembrace.com.

ACCESS PATHWAYS[®]
PROGRAM

How to save on Zembrace[®] SymTouch[®]

The Access Pathways[®] Program is a dedicated savings and support program to help you access Zembrace[®] SymTouch[®] for as little as \$0.*

Access Pathways[®], in partnership with BlinkRx, offers:

\$0*

Eligible, commercially ensured patients may pay as little as \$0* per prescription, per month.



Fast, free
home delivery.



Dedicated customer support to
guide you through the process.



*Restrictions and quantity limits apply. Visit [Zembrace.com](https://www.zembrace.com) to view complete program terms and conditions. Medicare, Medicaid, and other federal and state healthcare program patients are not eligible.

**Please see Important Safety Information on
pages 12 to 15 and full Prescribing Information,
including Patient Information and Instructions
for Use at [Zembrace.com](https://www.zembrace.com).**

IMPORTANT SAFETY INFORMATION

Zembrace SymTouch (Zembrace) can cause serious side effects, including heart attack and other heart problems, which may lead to death. Stop use and get emergency help if you have any signs of a heart attack:

- discomfort in the center of your chest that lasts for more than a few minutes or 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

Zembrace is not for people with risk factors for heart disease (high blood pressure or cholesterol, smoking, overweight, diabetes, family history of heart disease) unless a heart exam shows no problem.

Do not use Zembrace if you have:

- history of heart problems
- narrowing of blood vessels to your legs, arms, stomach, or kidney (peripheral vascular disease)
- uncontrolled high blood pressure
- hemiplegic or basilar migraines. If you are not sure if you have these, ask your provider.

- had a stroke, transient ischemic attacks (TIAs), or problems with blood circulation
- severe liver problems
- taken any of the following medicines in the last 24 hours: almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, ergotamines, dihydroergotamine.
- are taking certain antidepressants, known as monoamine oxidase (MAO)-A inhibitors or it has been 2 weeks or less since you stopped taking a MAO-A inhibitor. Ask your provider for a list of these medicines if you are not sure.
- an allergy to sumatriptan or any of the components of Zembrace

Tell your provider about all of your medical conditions and medicines you take, including vitamins and supplements.

Zembrace can cause dizziness, weakness, or drowsiness. If so, do not drive a car, use machinery, or do anything where you need to be alert.

Zembrace may cause serious side effects including:

- changes in color or sensation in your fingers and toes
- sudden or severe stomach pain, stomach pain after meals, weight loss, nausea or vomiting, constipation or diarrhea, bloody diarrhea, fever

***Important Safety Information
continued on next page.***

- 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 one or both legs or feet
- increased blood pressure including a sudden severe increase even if you have no history of high blood pressure
- medication overuse headaches from using migraine medicine for 10 or more days each month. If your headaches get worse, call your provider.
- serotonin syndrome, a rare but serious problem that can happen in people using Zembrace, especially when used with anti-depressant medicines called SSRIs or SNRIs. Call your provider right away if you have: 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; or trouble walking.
- hives (itchy bumps); swelling of your tongue, mouth, or throat
- seizures even in people who have never had seizures before

The most common side effects of Zembrace include: pain and redness at 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 provider if you have any side effect that bothers you or does not go away. These are not all the possible side effects of Zembrace. For more information, ask your provider.

This is the most important information to know about Zembrace but is not comprehensive. For more information, talk to your provider and read the **Patient Information** and **Instructions for Use**. You can also visit www.tonixpharma.com or call 1-888-650-3789.

You are encouraged to report adverse effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

INDICATION AND USAGE

Zembrace is a prescription medicine used to treat acute migraine headaches with or without aura in adults who have been diagnosed with migraine.

Zembrace is not used to prevent migraines. It is not known if it is safe and effective in children under 18 years of age.



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Learn more about
Zembrace[®] SymTouch[®]
at **Zembrace.com**

References

1. Zembrace SymTouch [package insert]. Catham, NJ: Tonix Medicines, Inc.: February 2021.
2. Mathew NT, et al. Dose ranging efficacy and safety of subcutaneous sumatriptan in the acute treatment of migraine. US Sumatriptan Research Group. *Arch Neurol*. 1992;49(12):1271-1276.
3. Top 10 migraine triggers and how to deal with them. American Migraine Foundation. <https://americanmigrainefoundation.org/resource-library/top-10-migraine-triggers-and-how-to-deal-with-them/>. Published July 27, 2017. Accessed 2021.
4. Newman LC. Why triptan treatment can fail: focus on gastrointestinal manifestations of migraine. *Headache*. 2013;53 Suppl 1:11-16.
5. Data on file. Catham, NJ: Tonix Medicines, Inc.: 2021.
6. Brand-Schieber E, Munjal S, Kumar R, et al. Human factors validation study of 3 mg sumatriptan autoinjector, for migraine patients. *Med Devices (Auckl)*. 2016;9:131-137.



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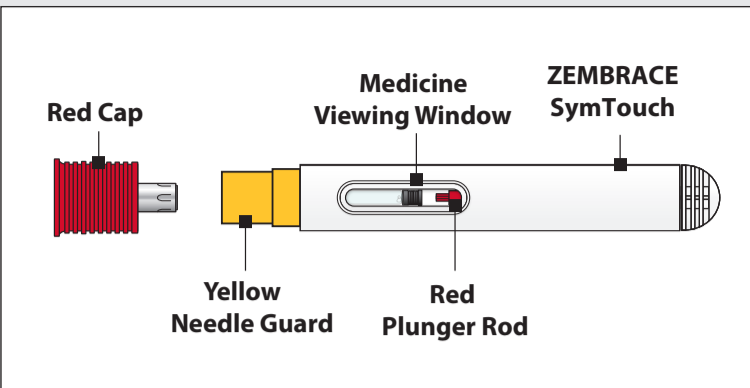
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PM-002276.01

Read this Instructions for Use before you start to use the ZEMBRACE® SymTouch®. 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 ZEMBRACE SymTouch when you start taking it and at regular checkups.

The ZEMBRACE SymTouch Auto-injector is a single-use, pre-filled injection device with the exact dose you need. The device should be used only 1 time and then discarded.

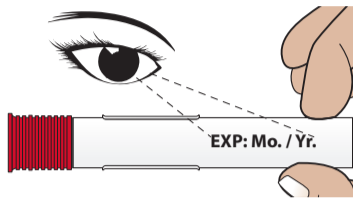
⚠ Important Precautions

- Keep out of reach of children.
- Do not use after the expiration date has passed.**
- Do not store or expose to high temperatures.**
- Do not freeze.**
- Do not remove the Red Cap until you are ready to inject.**
- Do not use if dropped after removing the Red Cap.**
- Do not put or press thumb, fingers or hand over the Yellow Needle Guard.**



Step 1 - Inspect Auto-injector and Gather Supplies

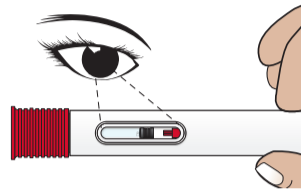
- ▶ **1A - Remove Auto-injector from the carton**
- ▶ **1B - Check the Expiration Date on the Auto-injector**
- ▶ **1C - Inspect the medicine through the Medicine Viewing Window**
- ▶ **1D - Gather the following supplies**



Do not use if the expiration date has passed.

Inspect the appearance of ZEMBRACE SymTouch Auto-injector medicine through the medicine viewing window. It must be a clear, colorless to pale yellow solution.

Do not inject the medicine if the solution looks discolored or cloudy or contains lumps, flakes, or particles.

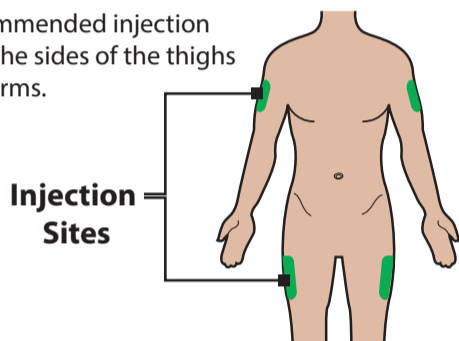


1. Auto-injector
 2. Alcohol Swab
 3. Sterile Cotton Ball or Gauze
 4. Puncture-Resistant Sharps Container
-

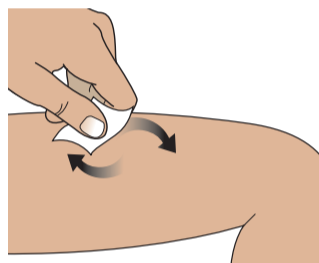
Step 2 - Choose and Prepare Your Injection Site

- ▶ **2A - Choose your injection site**
- ▶ **2B - Clean the injection site with an alcohol swab**
- ▶ **2C - Remove the Red Cap**

The recommended injection sites are the sides of the thighs and the arms.

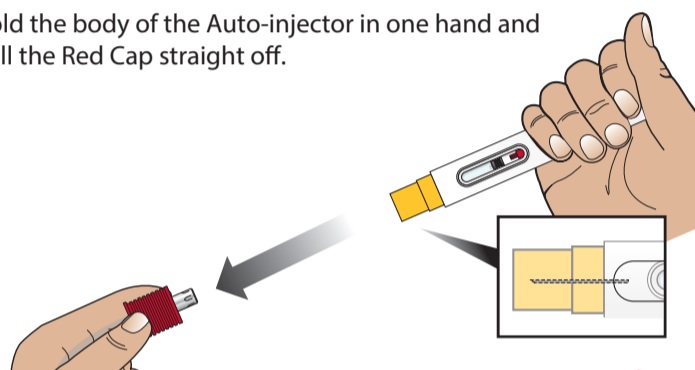


Caution: Do not inject where your skin is scarred, bruised, tender, red or near any open wound.



Do not touch injection site area after cleaning.

Hold the body of the Auto-injector in one hand and pull the Red Cap straight off.



Warning: Do not put or press thumb, fingers or hand over the Yellow Needle Guard, doing so may result in a needle stick injury.

Step 3 - Inject the Medicine

- ▶ **3A - Place Auto-injector straight on your injection site**
- ▶ **3B - Perform Injection**
- ▶ **3C - Remove Auto-injector from skin**

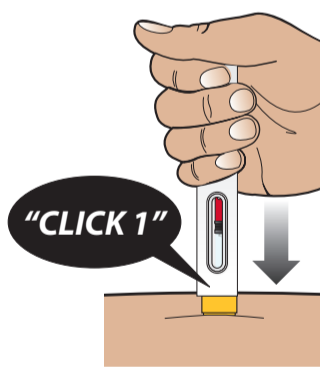
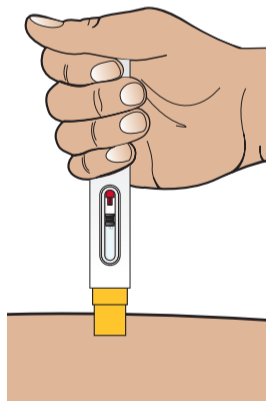
Place the Auto-injector straight on your injection site (90 degrees) with the Yellow Needle Guard end gently pressed against your skin.

Press and hold the Auto-injector down against your skin. You will hear the first "Click 1" as the injection starts. Continue to hold the device down until you hear the second "Click 2."

Wait 5 seconds before you remove the Auto-injector!

After "Click 2," continue to hold down and slowly count to 5 to make sure you receive your full dose.

Remove the Auto-injector by lifting it straight away from your skin. The Yellow Needle Guard will drop down and lock over the needle.

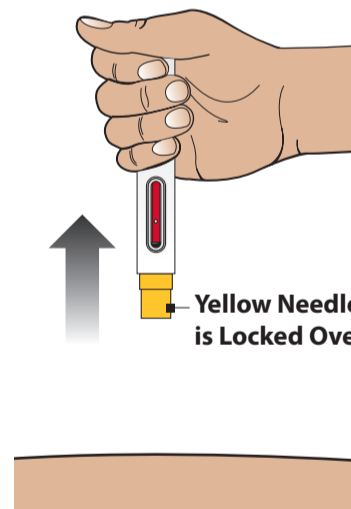


HOLD!



WAIT!

CONTINUE TO HOLD DOWN AND SLOWLY COUNT TO 5.
⌚ 1...2...3...4...5



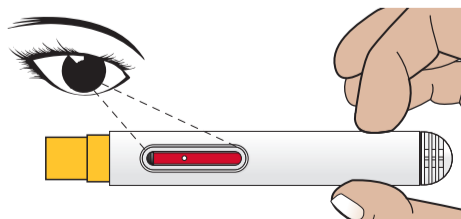
Yellow Needle Guard is Locked Over Needle

Important: To receive your full dose, always hold the Auto-injector down on your injection site for additional time after you hear the second click. This allows all of the medicine to be delivered.

Step 4 - Confirm Injection and Dispose the Auto-injector

- ▶ **4A - Confirm Red Color in Medicine Viewing Window**
- ▶ **4B - Disposal of the Auto-injector**
- ▶ **4C - Treat Injection Site**

Look to confirm that the Red Plunger Rod has filled the Medicine Viewing Window. This means you received the full dose.



Caution: Call your healthcare provider if the Red Plunger Rod has not filled the Medicine Viewing Window. This may mean that only a partial dose was delivered.

Do not try to reuse the Auto-injector.

Put your used Auto-injector, caps, needles, and sharps in an FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and syringes in your household trash. Do not recycle your used sharps disposal container.

If you do not have a FDA-cleared sharps disposal container, you may use a household container that is: made of a heavy-duty plastic; can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out; upright and stable during use; leak-resistant; and 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 syringes. 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.

If needed, make sure you get a refill of your Auto-injector.



Treat the injection site with a cotton ball, gauze pad or bandage, as needed.

Do not rub the injection site.

Manufactured for **Tonix Medicines, Inc.**
Chatham, NJ 07928

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

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