

Patient Information
TOSYMRA (toe-SIM-ruh)
(sumatriptan)
Nasal Spray

What is the most important information I should know about TOSYMRA?

TOSYMRA can cause serious side effects, including:

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

Stop taking TOSYMRA 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

TOSYMRA 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 TOSYMRA?

TOSYMRA is a prescription medicine used to treat acute migraine headaches with or without aura in adults.

TOSYMRA 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.

TOSYMRA is not used to prevent or decrease the number of migraines you have.

TOSYMRA is not used to treat cluster headaches.

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

Do not take TOSYMRA if you have:

- heart problems or a history of heart problems
- narrowing of blood vessels to your legs, arms, stomach, or kidney (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
- eletriptan
- frovatriptan
- naratriptan
- rizatriptan
- ergotamines
- dihydroergotamine

Ask your healthcare provider if you are not sure if your medicine is listed above.

- 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 healthcare provider or pharmacist for a list of these medicines if you are not sure.
- an allergy to sumatriptan or any of the ingredients in TOSYMRA. See the end of this Patient Information leaflet for a complete list of ingredients in TOSYMRA.

Before taking TOSYMRA, 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.
- are pregnant or plan to become pregnant. It is not known if TOSYMRA can harm your unborn baby.
- are breastfeeding or plan to breastfeed. TOSYMRA 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 TOSYMRA.

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

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

Especially tell your healthcare provider if you take anti-depressant 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 TOSYMRA?

- See the Instructions for Use for complete information on how to use TOSYMRA nasal spray.
- Certain people should take their first dose of TOSYMRA 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 TOSYMRA exactly as your healthcare provider tells you to use it.
- You should take TOSYMRA as soon as the symptoms of your headache start, but it may be taken at any time during a migraine.
- If your headache comes back after the first nasal spray or you only get some relief from your headache, you can use a second nasal spray 1 hour after the first nasal spray.
- Do not use more than 30 mg of TOSYMRA Nasal Spray in a 24-hour period.
- If you use too much TOSYMRA, 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 TOSYMRA so you can talk with your healthcare provider about how TOSYMRA is working for you.

What should I avoid while taking TOSYMRA?

TOSYMRA 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 TOSYMRA?

TOSYMRA may cause serious side effects. See “What is the most important information I should know about TOSYMRA?”

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 much migraine medicine, such as TOSYMRA, for 10 or more days each month may have worse headaches (medication overuse headache). If your headaches get worse, your healthcare provider may decide to stop your treatment with TOSYMRA.
- serotonin syndrome. Serotonin syndrome is a rare but serious problem that can happen in people using TOSYMRA, especially if TOSYMRA 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
- increased blood pressure including a sudden severe increase (hypertensive crisis) even if you have no history of high blood pressure.
- hives (itchy bumps); swelling of your tongue, mouth, or throat.
- seizures. Seizures have happened in people taking TOSYMRA who have never had seizures before. Talk with your healthcare provider about your chance of having seizures while you take TOSYMRA.

The most common side effects of TOSYMRA include:

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| ● tingling | ● dizziness | ● feeling warm or hot | ● burning feeling |
| ● feeling of heaviness | ● feeling of pressure | ● flushing | ● feeling of tightness |
| ● numbness | ● application site (nasal) reactions | ● abnormal taste | ● throat irritation |

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 TOSYMRA. For more information, ask your healthcare provider or pharmacist.

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 TOSYMRA?

- Store between 68° to 77°F (20° to 25°C)
- Do not store in the refrigerator or freeze.
- Do not test before use.

Keep TOSYMRA and all medicines out of the reach of children.

General information about the safe and effective use of TOSYMRA.

Medicines are sometimes prescribed for purposes other than those listed in Patient Information leaflets. Do not use TOSYMRA for a condition for which it was not prescribed. Do not give TOSYMRA to other people, even if they have the same symptoms you have. It may harm them.

You can ask your healthcare provider or pharmacist for information about TOSYMRA that is written for healthcare professionals.

What are the ingredients in TOSYMRA?

Active ingredient: sumatriptan

Inactive ingredients: citric acid monohydrate, n-Dodecyl beta-D-maltoside, potassium phosphate monobasic, sodium chloride, and sodium phosphate dibasic anhydrous in water for injection.

Manufactured for: Dr. Reddy's Laboratories Limited.

Distributed by: Promius Phama, LLC., Princeton, NJ 08540

For more information, go to www.drreddys.com or call 1-888-966-8766.

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

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