



Patient Information

Rizatriptan (rye™ za trip' tan ben' zoe ate) Benzoate Tablets

Read this Patient Information before you start taking rizatriptan benzoate tablets and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

What are rizatriptan benzoate tablets?

Rizatriptan benzoate tablets are a prescription medicine that belongs to a class of medicines called Triptans. Rizatriptan benzoate tablets are available as a traditional tablet and as an orally disintegrating tablet.

Rizatriptan benzoate tablets are used to treat migraine attacks with or without aura in adults and in children 6 to 17 years of age.

Rizatriptan benzoate tablets are not to be used to prevent migraine attacks.

Rizatriptan benzoate tablets are not for the treatment of hemiplegic or basilar migraines.

It is not known if rizatriptan benzoate tablets are safe and effective for the treatment of cluster headaches.

It is not known if taking more than 1 dose of rizatriptan benzoate tablets in 24 hours is safe and effective in children 6 to 17 years of age.

It is not known if rizatriptan benzoate tablets are safe and effective in children under 6 years of age.

Who should not take rizatriptan benzoate tablets?

Do not take rizatriptan benzoate tablets if you:

- have or have had heart problems
- have or have had a stroke or a transient ischemic attack (TIA)
- have or have had blood vessel problems including ischemic bowel disease
- have uncontrolled high blood pressure
- have taken other Triptan medicines in the last 24 hours
- have taken ergot-containing medicines in the last 24 hours
- have hemiplegic or basilar migraines
- take monoamine oxidase (MAO) inhibitor or have taken a MAO inhibitor within the last 2 weeks
- are allergic to rizatriptan benzoate or any of the ingredients in rizatriptan benzoate tablets. See the end of this leaflet for a complete list of ingredients in rizatriptan benzoate tablets.

Talk to your doctor before taking this medicine if you have any of the conditions listed above or if you are not sure if you take any of these medicines.

What should I tell my doctor before taking rizatriptan benzoate tablets?

Before you take rizatriptan benzoate tablets, tell your doctor if you:

- have or have had heart problems, high blood pressure, chest pain, or shortness of breath
- have any risk factors for heart problems or blood vessel problems such as:
 - o high blood pressure
 - o high cholesterol
 - o smoking
 - o obesity
 - o diabetes
 - o family history of heart problems
 - o you are post menopausal
 - o you are a male over 40

- have kidney or liver problems
- have any other medical condition
- are pregnant or plan to become pregnant. It is not known if rizatriptan benzoate tablets will harm your unborn baby. If you become pregnant while taking rizatriptan benzoate tablets, talk to your healthcare provider
- are breastfeeding or plan to breastfeed. It is not known if rizatriptan benzoate passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take rizatriptan benzoate tablets.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

Rizatriptan benzoate tablets and other medicines may affect each other causing side effects. Rizatriptan benzoate tablets may affect the way other medicines work, and other medicines may affect how rizatriptan benzoate tablets work.

Especially tell your doctor if you take:

- propranolol containing medicines such as Inderal[®], Inderal[®] LA[†], or Innopran[®] XL[†]
- medicines used to treat mood disorders, including selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs).

Ask your doctor 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 doctor and pharmacist when you get a new medicine.

How should I take rizatriptan benzoate tablets?

- Take rizatriptan benzoate tablets exactly as your doctor tells you to take it.
- Your doctor will tell you how much rizatriptan benzoate tablets to take and when to take it.
- If your headache comes back after your first rizatriptan benzoate tablets dose:
 - o For adults: a second dose may be taken 2 hours after the first dose. Do not take more than 30 mg of rizatriptan benzoate tablets in a 24-hour period (for example, do not take more than three 10 mg tablets in a 24-hour period).
 - o For children 6 to 17 years of age: It is not known if taking more than 1 dose of rizatriptan benzoate tablets in 24 hours is safe and effective. Talk to your doctor about what to do if your headache does not go away or comes back.
- If you take too much rizatriptan benzoate tablets, call your doctor or go to the nearest hospital emergency room right away.

What should I avoid while taking rizatriptan benzoate tablets?

Rizatriptan benzoate tablets may cause dizziness, weakness, or fainting. If you have these symptoms, do not drive a car, use machinery, or do anything that needs you to be alert.

What are the possible side effects of rizatriptan benzoate tablets?

Rizatriptan benzoate tablets may cause serious side effects. Call your doctor or go to the nearest hospital emergency room right away if you think you are having any of the serious side effects of rizatriptan benzoate tablets including:

- **heart attack.** Symptoms of a heart attack may include:
 - o chest discomfort in the center of your chest that lasts for more than a few minutes or that goes away and comes back
 - o chest discomfort that feels like uncomfortable pressure, squeezing, fullness or pain
 - o pain or discomfort in your arms, back, neck, jaw or stomach
 - o shortness of breath with or without chest discomfort
 - o breaking out in a cold sweat
 - o nausea or vomiting
 - o feeling lightheaded

- **stroke.** Symptoms of a stroke may include the following sudden symptoms:
 - o numbness or weakness in your face, arm or leg, especially on one side of your body
 - o confusion, problems speaking or understanding
 - o problems seeing in 1 or both of your eyes
 - o problems walking, dizziness, loss of balance or coordination
 - o severe headache with no known cause
- **blood vessel problems.** Symptoms of blood vessel problems may include:
 - o stomach pain
 - o bloody diarrhea
 - o vision problems
 - o coldness and numbness of hands and feet
- **serotonin syndrome.** A condition called serotonin syndrome can happen when Triptan medicines such as rizatriptan benzoate tablets are taken with certain other medicines. Symptoms of serotonin syndrome may include:
 - o agitation
 - o hallucinations
 - o coma
 - o fast heartbeat
 - o fast changes in your blood pressure
 - o increased body temperature
 - o muscle spasm
 - o loss of coordination
 - o nausea, vomiting or diarrhea

- **increased blood pressure**

The most common side effects of rizatriptan benzoate tablets in adults include:

- feeling sleepy or tired
- pain or pressure in your chest or throat
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away.

If you take rizatriptan benzoate tablets too often, this may result in you getting chronic headaches. In such cases, you should contact your doctor, as you may have to stop taking rizatriptan benzoate tablets.

These are not all the possible side effects of rizatriptan benzoate tablets. For more information, ask your doctor 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 rizatriptan benzoate tablets?

- Store rizatriptan benzoate tablets at 68°F to 77°F (20°C to 25°C).
- Safely throw away medicine that is out of date or no longer needed.

Keep rizatriptan benzoate tablets and all medicines out of the reach of children.

General Information about the safe and effective use of rizatriptan benzoate tablets.

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

This Patient Information leaflet summarizes the most important information about rizatriptan benzoate tablets. If you would like more information, talk to your doctor. You can ask your pharmacist or doctor for information about rizatriptan benzoate tablets that is written for health professionals.

For more information call 1-800-367-3395 or go to www.bpirx.com. or go to www.fda.gov/medwatch, or call FDA at 1-800-FDA-1088.

What are the ingredients in rizatriptan benzoate tablets?

Active ingredient in rizatriptan benzoate tablets:

Rizatriptan benzoate, USP

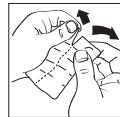
Inactive ingredients in rizatriptan benzoate tablets: ferric oxide (red), lactose monohydrate, magnesium stearate, microcrystalline cellulose and pregelatinized starch.

*The brand names mentioned are registered trademarks of their respective manufacturers.

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

How should I open rizatriptan benzoate tablets from child-resistant blister?

- Separate each unit of the blister individually through perforation and peel the lidding foil from "PEEL HERE" portion.
- Do not push rizatriptan benzoate tablets through the foil, may cause the tablet to break.



1. Pull apart one blister unit from the blister pack by tearing along the dotted lines (perforations) until it is fully separated.

2. Peel off the lidding foil from "PEEL HERE" portion.

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