



PACKAGE LEAFLET: INFORMATION FOR THE USER

Rizatriptan 10 mg orodispersible tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Rizatriptan is and what it is used for
2. What you need to know before you take Rizatriptan
3. How to take Rizatriptan
4. Possible side effects
5. How to store Rizatriptan
6. Contents of the pack and other information

1. WHAT RIZATRIPTAN IS AND WHAT IT IS USED FOR

Rizatriptan belongs to a class of medicines called selective serotonin 5-HT_{1B/1D} receptor agonists.

Rizatriptan is used to treat the headache phase of the migraine attack in adults.

Treatment with Rizatriptan:

Reduces swelling of blood vessels surrounding the brain. This swelling results in the headache pain of a migraine attack.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RIZATRIPTAN

Do not take Rizatriptan:

- if you are allergic to rizatriptan benzoate or any of the other ingredients of this medicine (listed in section 6).
- you have moderately severe or severe high blood pressure, or mild high blood pressure that is not controlled by medication
- you have or have ever had heart problems including heart attack or pain on the chest (angina) or you have experienced heart disease related signs
- you have severe liver or severe kidney problems
- you have had a stroke (cerebrovascular accident CVA) or mini stroke (transient ischaemic attack TIA)
- you have blockage problems with your arteries (peripheral vascular disease)
- you are taking monoamine oxidase (MAO) inhibitors such as moclobemide, phenelzine, tranylcypromine, or pargyline (drugs against depression), or linezolid (an antibiotic), or if it has been less than two weeks since you stopped taking MAO inhibitors
- you are now taking ergotamine-type medications, such as ergotamine or dihydro-ergotamine to treat your migraine or methysergide to prevent a migraine attack
- you are taking any other drug in the same class, such as sumatriptan, naratriptan or zolmitriptan to treat your migraine. (See Taking with other medicines below)

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Rizatriptan.

Warnings and precautions

Talk to your doctor or pharmacist before taking Rizatriptan if:

- you have any of the following risk factors for heart disease: high blood pressure, diabetes, you smoke or you are using nicotine substitution, your family has a history of heart disease, you are a man over 40 years of age, or you are a post-menopausal woman
- you have kidney or liver problems
- you have a particular problem with the way your heart beats (bundle branch block)
- you have or have had any allergies.
- your headache is associated with dizziness, difficulty in walking, lack of co-ordination or weakness in the leg and arm
- you use herbal preparation containing St. John's wort
- you have had allergic reaction like swelling of face, lips, tongue and/or throat which may cause difficulty breathing and/or swallowing (angioedema).
- you are taking selective serotonin reuptake inhibitors (SSRIs) such as sertraline, escitalopram oxalate, and fluoxetine or serotonin norepinephrine reuptake inhibitors (SNRIs) such as venlafaxine, and duloxetine for depression.
- you have had short lived symptoms including chest pain and tightness.

If you take Rizatriptan too often this may result in you getting a chronic headache. In such cases you should contact your doctor as you may have to stop taking Rizatriptan.

Please tell your doctor or pharmacist about your symptoms. Your doctor will decide if you have migraine. You should take Rizatriptan only for a migraine attack. Rizatriptan should not be used to treat headaches that might be caused by other, more serious conditions.

Please tell your doctor if you are taking or have recently taken or plan to take, any other medicines including medicines obtained without a prescription. This includes herbal medicines and those you normally take for a migraine. This is because Rizatriptan can affect the way some medicines work. Also other medicines can affect Rizatriptan.

Other medicines and Rizatriptan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Rizatriptan:

- if you are already taking a 5HT_{1B/1D} agonist (sometimes referred to as 'triptans'), such as sumatriptan, naratriptan or zolmitriptan.
- if you are taking a monoamine oxidase (MAO) inhibitor such as moclobemide, phenelzine, tranylcypromine, linezolid, or pargyline or if it has been less than two weeks since you stopped taking an MAO inhibitor.
- if you use ergotamine-type medications such as ergotamine or dihydro-ergotamine to treat your migraine
- if you use methysergide to prevent a migraine attack.

The above listed medicines when taken with Rizatriptan may increase the risk of side effects.

You should wait at least 6 hours after taking Rizatriptan before you take ergotamine-type medications such as ergotamine or dihydro-ergotamine or methysergide.

You should wait at least 24 hours after taking ergotamine-type medications before taking Rizatriptan.

Ask your doctor for instructions and the risks about taking Rizatriptan

- if you are taking propranolol (see section 3: How to take Rizatriptan)
- if you are taking SSRIs such as sertraline, escitalopram oxalate, and fluoxetine or SNRIs such as venlafaxine, and duloxetine for depression.

Rizatriptan with food and drink

Rizatriptan can take longer to work if it is taken after food. Although it is better to take it on an empty stomach, you can still take it if you have eaten.

Pregnancy breast-feeding and fertility

It is not known whether Rizatriptan is harmful to an unborn baby when taken by a pregnant woman.

Talk to your doctor before taking this medicine if you are pregnant, planning to get pregnant or are breastfeeding. Breastfeeding should be avoided for 24 hours after treatment.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Use in children

The use of Rizatriptan in children under 18 years of age is not recommended.

Use in patients older than 65 years

There have been no full studies to look at how safe and effective Rizatriptan is amongst patients older than 65 years.

Driving or using machines

You may feel sleepy or dizzy while taking Rizatriptan. If this happens, do not drive or use any tools or machines.

Rizatriptan contains Aspartame

Rizatriptan contains aspartame, a source of phenylalanine. This may be harmful for people with phenylketonuria.

3. HOW TO TAKE RIZATRIPTAN

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Rizatriptan is used to treat migraine attacks. Take Rizatriptan as soon as possible after your migraine headache has started. Do not use it to prevent an attack.

The usual dose is 10 mg.

If you are currently taking propranolol or have kidney or liver problems you should use the 5-mg dose of rizatriptan. You should leave at least 2 hours between taking propranolol and Rizatriptan up to a maximum of 2 doses in a 24-hour period.

If migraine returns within 24 hours

In some patients, migraine symptoms can return within a 24-hour period. If your migraine does return you can take an additional dose of Rizatriptan. You should always wait at least 2 hours between doses.

