

PACKAGE LEAFLET

Package leaflet: Information for the patient
Rizatriptan 10 mg Orodispersible Tablets
(rizatriptan)

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. See section 4.

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
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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. Do not use it to prevent an attack.

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 (hypersensitive) to rizatriptan benzoate or any of the other ingredients of this medicine (listed in section 6)
- have moderately severe or severe high blood pressure or mild high blood pressure that is not controlled by medication
- have or have ever had heart problems including heart attack or pain on the chest (angina) or you have experienced heart disease related signs
- have severe liver or severe kidney problems
- have had a stroke (cerebrovascular accident CVA) or mini stroke (transient ischaemic attack TIA)
- have blockage problems with your arteries (peripheral vascular disease)
- 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

- are now taking ergotamine-type medications, such as ergotamine or dihydroergotamine to treat your migraine or methysergide to prevent a migraine attack
- are taking any other drug in the same class, such as sumatriptan, naratriptan or zolmitriptan to treat your migraine (see **Other medicines and rizatriptan** 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

Before you take rizatriptan, tell your doctor or pharmacist, 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
- have kidney or liver problems
- have a particular problem with the way your heart beats (bundle branch block)
- have or have had any allergies
- have a headache which is associated with dizziness, difficulty in walking, lack of co-ordination or weakness in the leg and arm
- use herbal preparations containing St. John's wort
- have had allergic reaction like swelling of face, lips, tongue and/or throat which may cause difficulty breathing and/or swallowing (angioedema)
- 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
- 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.

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.

Other medicines and rizatriptan

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.

Do not take rizatriptan if you are taking

- a 5-HT_{1B/1D} agonist (sometimes referred to as 'triptans'), such as sumatriptan, naratriptan or zolmitriptan.
- 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.
- ergotamine-type medications such as ergotamine or dihydro-ergotamine to treat your migraine

- 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 How to take Rizatriptan)
- 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 and breast-feeding

If you are pregnant or breast-feeding, think you are pregnant or planning to have a baby. Ask your doctor or pharmacist for advice before taking this medicine. It is not known whether rizatriptan is harmful to an unborn baby when taken by pregnant women. Breastfeeding should be avoided for 24 hours after treatment.

Driving and using machines

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

Important information about some of the ingredients in Rizatriptan orodispersible tablets

Rizatriptan contains aspartame a source of phenylalanine which may be harmful for people with phenylketonuria. Each 10 mg tablet contains 2.0 mg of aspartame (which contains phenylalanine).

Rizatriptan also contains mannitol which may have a mild laxative effect. Each 10 mg tablet contains 91.620 mg of mannitol.

3. How to take Rizatriptan

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.

Always take rizatriptan exactly as your doctor has told you. You should check with your doctor or your pharmacist if you are not sure.

The recommended 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 upto 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.

If after 2 hours you still have a migraine

If you do not respond to the first dose of rizatriptan during an attack, you should not take a second dose of rizatriptan for treatment of the same attack. It is still likely, however, that you will respond to rizatriptan during the next attack.

Do not take more than 2 doses of rizatriptan in a 24-hour period, (for example, do not take more than two 10 mg orodispersible tablets or more than two 10 mg or 5 mg tablets in a 24-hour period). You should always wait at least 2 hours between doses.

If your condition worsens, seek medical attention.

How to take Rizatriptan orodispersible tablets

- Rizatriptan (rizatriptan benzoate) is available as a 5 or 10 mg orodispersible tablet that dissolves in the mouth.
- Open the blister with dry hands.
- The orodispersible tablet should be placed on your tongue, where it dissolves and can be swallowed with the saliva.
- The orodispersible tablet can be used in situations in which liquids are not available, or to avoid the nausea and vomiting that may accompany the ingestion of tablets with liquids.

Rizatriptan is also available as a tablet to be taken with liquids.

Use in children and adolescents

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

Use in patients older than 65 years

There are no full studies to assess the safety and efficacy of rizatriptan in patients over 65 years.

If you take more rizatriptan than you should:

If you take more rizatriptan than you should, talk to your doctor or pharmacist straight away. Take the medicine pack with you.

Signs of overdosage can include dizziness, drowsiness, vomiting, fainting and slow heart rate.

If you have any further questions on the use of this medicine ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. In adult studies, the most common side effects reported were dizziness, sleepiness and tiredness.

The following side effects may happen with this medicine

Common (affects 1 to 10 users in 100)

- tingling (paraesthesia), headache, decreased sensitivity of skin (hypoesthesia), decreased mental sharpness, insomnia
- fast or irregular heart beat (palpitation)
- flushing (redness of the face lasting a short time)
- throat discomfort
- feeling sick (nausea), dry mouth, vomiting, diarrhoea, indigestion (dyspepsia)
- feeling of heaviness in parts of the body, neck pain, stiffness
- pain in abdomen or chest

Uncommon (affects 1 to 10 users in 1000)

- bad taste in your mouth.
- unsteadiness when walking (ataxia), dizziness (vertigo), blurred vision, tremor, fainting (syncope)
- confusion, nervousness.
- high blood pressure (hypertension); thirst, hot flushes, sweating
- rash, itching and lumpy rash (hives); swelling of face, lips, tongue and/or throat which may cause difficulty breathing and/or swallowing (angioedema), difficulty breathing (dyspnoea)
- feeling of tightness in parts of the body, muscle weakness.
- changes in the rhythm or rate of the heartbeat (arrhythmia); abnormalities of the electrocardiogram (a test that records the electrical activity of your heart), very fast heartbeat (tachycardia)
- facial pain; muscle pain.

Rare (affects 1 to 10 users in 10,000)

- wheezing.
- allergic reaction (hypersensitivity); sudden life-threatening allergic reaction (anaphylaxis).
- stroke (this generally occurs in patients with risk factors for heart and blood vessel disease (high blood pressure, diabetes, smoking, use of nicotine substitution, family history of heart disease or stroke, man over 40 years of age, postmenopausal women, particular problem with the way your heart beats [bundle branch block]).
- slow heartbeat (bradycardia).

Not known (frequency cannot be estimated from the available data):

- heart attack, spasm of the blood vessels of the heart (these generally occur in patients with risk factors for heart and blood vessel disease (high blood pressure, diabetes, smoking, use of nicotine substitution, family history of heart disease or stroke, man over 40 years of age, postmenopausal women, particular problem with the way your heart beats [bundle branch block])).

- a syndrome called "serotonin syndrome" that may cause side effects like coma, unstable blood pressure, extremely high body temperature, lack of muscle coordination, agitation, and hallucinations.
- severe shedding of the skin with or without fever (toxic epidermal necrolysis),
- seizure (convulsions/fits).
- spasm of blood vessels of the extremities including coldness and numbness of the hands or feet.
- spasm of the blood vessels of the colon (large bowel), which can cause abdominal pain.

Tell your doctor right away if you have symptoms of allergic reactions, serotonin syndrome, heart attack or stroke

In addition, tell your doctor if you experience any symptoms that suggest an allergic reaction (such as a rash or itching) after taking rizatriptan

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store rizatriptan

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of the month.

Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Rizatriptan orodispersible Tablet contains

- The active substance is rizatriptan. One orodispersible tablet contains 10 mg rizatriptan as 14.530 mg of rizatriptan benzoate.
- The other ingredients are mannitol (E 421), calcium silicate (E 552), crospovidone, aspartame (E 951), peppermint flavor, silica colloidal anhydrous, sodium stearyl fumarate

What Rizatriptan orodispersible tablet looks like and content of the pack

Rizatriptan 10 mg Orodispersible tablets are white, round, flat faced beveled edge tablets, debossed with "HP" on one side and "239" on other side.

Rizatriptan 10mg Orodispersible tablets are available in perforated unit-dose blister packs of 2, 3, 6, 12 and 18 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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