

Rizatriptan 10mg 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 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.
- The full name of this medicine is Rizatriptan 10mg Orodispersible Tablets but within the leaflet it will be referred to as Rizatriptan tablets.

What is in this leaflet:

- 1 What Rizatriptan tablets are and what they are used for**
- 2 What you need to know before you take Rizatriptan tablets**
- 3 How to take Rizatriptan tablets**
- 4 Possible side effects**
- 5 How to store Rizatriptan tablets**
- 6 Contents of the pack and other information**

1 What Rizatriptan tablets are and what they are used for

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

Your doctor has prescribed Rizatriptan tablets to treat the headache phase of your migraine attack.

Treatment with Rizatriptan tablets 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 tablets

Do not take Rizatriptan tablets if you:

- are **allergic** 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 dihydro-ergotamine 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 "Taking 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 tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Rizatriptan tablets 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 preparations containing **St. John's wort** (may increase the risk of side effects)
- you have had **allergic** reaction like swelling of the 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 noradrenaline 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 tablets 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 tablets.

Please tell your doctor or pharmacist about your symptoms. Your doctor will decide if you have migraine. You should take Rizatriptan tablets only for a migraine attack. Rizatriptan tablets 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 tablets can affect the way some medicines work. Other medicines can also affect Rizatriptan tablets.

Other medicines and Rizatriptan tablets

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

Do not take Rizatriptan tablets:

- if you are already taking a 5-HT_{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 tablets may increase the risk of side effects.

You should wait at least 6 hours after taking Rizatriptan tablets 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 tablets.

Ask your doctor for instructions and the risks about taking Rizatriptan tablets:

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

Rizatriptan tablets with food and drink:

Rizatriptan tablets 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 may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

Breast-feeding should be avoided for 24 hours after treatment.

Ask your doctor or pharmacist for advice before taking any medicine.

Children and adolescents

The use of Rizatriptan tablets 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 tablets are amongst patients older than 65 years.

Driving and using machines

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

Rizatriptan tablets contain mannitol and a source of phenylalanine

Mannitol may have a mild laxative effect.

This medicine contains 8.8 mg aspartame in each tablet which is equivalent to 4.9 mg phenylalanine. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3 How to take Rizatriptan tablets

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

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

The recommended dose is 10mg (one Rizatriptan 10mg Orodispersible Tablet).

If you are currently taking propranolol or have kidney or liver problems you should use a 5mg 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.

Rizatriptan tablets (rizatriptan benzoate) dissolve in the mouth.

- Open the Rizatriptan tablets blister pack with dry hands
- The orodispersible tablet should be placed on your tongue, where it dissolves and can be swallowed with the saliva
- The orodispersible tablets 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.

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

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

If your condition worsens, seek medical attention.

If you take more Rizatriptan tablets than you should:

If you take more Rizatriptan tablets 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 product, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Rizatriptan tablets and tell your doctor or go to your nearest hospital emergency department immediately if you experience any of the following serious side effects:

- an **allergic reaction** like swelling of the face, lips, tongue and/or throat which may cause difficulty breathing (dyspnoea) and/or swallowing (angioedema); rashes including itching and lumpy rash (hives); severe shedding of the skin including accompanied by fever (**toxic epidermal necrolysis**)
- 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**); slow heartbeat (**bradycardia**)
- **stroke; 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, post-menopausal 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 co-ordination, agitation, and hallucinations
- **seizure** (convulsions/fits).

Other possible side effects:

Common (may affect up to 1 in 10 people):

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

Uncommon (may affect up to 1 in 100 people):

- disorientation, nervousness
- unsteadiness when walking (ataxia), dizziness (vertigo), bad taste in your mouth, tremor, fainting
- blurred vision
- high blood pressure (hypertension), hot flushes
- thirst, sweating
- feeling of tightness in parts of the body, muscle weakness
- facial pain, muscle pain.

Rare (may affect up to 1 in 1,000 people):

- wheezing.

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

- 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.

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 tablets

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 pack and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 tablets contain

The active substance is rizatriptan.

One Rizatriptan 10mg Orodispersible Tablet contains 10mg rizatriptan as 14.53mg of rizatriptan benzoate.

The other ingredients are: mannitol (E421), microcrystalline cellulose, calcium silicate, crospovidone type A (E1202), aspartame (E951), colloidal anhydrous silica, peppermint flavour and magnesium stearate (E470b).

What Rizatriptan tablets look like and contents of the pack

Rizatriptan 10mg Orodispersible Tablets are white, round, 9mm in diameter, flat, bevel-edged tablets, with “IZ 10” engraved on one side.

OPA/Aluminium/PVC-Aluminium blister packs with push-through foil.

Pack sizes: 3 and 6 orodispersible tablets

Marketing Authorisation Holder

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Manufacturer

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