

Package Leaflet: Information for the User

Rizatriptan 5 mg and 10 mg 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 of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

What is in this leaflet:

1. What Rizatriptan Tablet is and what it is 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 Tablet 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. Do not use it to prevent an attack.

2. What you need to know before you take

Rizatriptan Tablets Do not take this medicine if:

- you are allergic to rizatriptan benzoate or any of the other ingredients in 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 **Other medicines and Rizatriptan Tablets** below)

If you are not sure if any of the above apply to you talk to your doctor or pharmacist before taking this medicine

Warnings and precautions:

Talk to your doctor or pharmacist before you take Rizatriptan Tablets. 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 postmenopausal 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 this medicine 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 this medicine.

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

Tell your doctor or pharmacist if you are taking or have recently taken, or might 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. Also, other medicines can affect this medicine.

Other medicines and Rizatriptan Tablets

Do not take this medicine

- 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 this medicine 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 this medicine

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.

Children and adolescents

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

Rizatriptan Tablets with food and drink

This medicine 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 planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

It is not known whether Rizatriptan Tablets is harmful to an unborn baby when taken by a pregnant woman. Breastfeeding should be avoided for 24 hours after treatment.

Use in patients older than 65 years

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

Driving or 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 contains lactose monohydrate

The 5 mg tablet contains 47.435 mg of lactose monohydrate and the 10 mg tablet contains 94.870 mg of lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Rizatriptan Tablets

Rizatriptan Tablets is used to treat migraine attacks. Take this medicine as soon as possible after your migraine headache has started.

Always take this medicine exactly as your doctor has told you. You should check with

your doctor or your pharmacist if you are not sure.

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 Tablets. You should leave at least 2 hours between taking propranolol and Rizatriptan Tablets up to a maximum of 2 doses in a 24-hour period.

Rizatriptan Tablets should be taken by mouth and swallowed whole with liquid.

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 this medicine for treatment of the same attack. It is still likely, however, that you will respond to this medicine during the next attack.

Do not take more than 2 doses of this medicine in a 24-hour period, (for example, do not take 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.

If you take more Rizatriptan Tablets than you should:

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

Signs of overdose 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.

Common (affects 1 to 10 people in 100)

- dizziness, tingling sensations (paraesthesia), headache, decreased sensitivity of skin (hypoesthesia), decreased mental sharpness, difficulty sleeping, sleepiness or tiredness,
- feeling your 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 people in 1000)

- bad taste in your mouth.
- unsteadiness when walking (ataxia), loss of balance, feeling giddy or dizzy (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 people in 10,000)

- wheezing,
- allergic reactions (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, post-menopausal 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 this medicine

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 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 carton/blister after "EXP". The expiry date refers to the last day of the month.

This medicinal product 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 contains

- The active substance of Rizatriptan Tablets is rizatriptan. One tablet contains 5 mg or 10 mg rizatriptan as 7.265 or 14.53 mg of rizatriptan benzoate.
- The other ingredients are: lactose monohydrate, cellulose microcrystalline (E460), starch, pregelatinised (E1401), iron oxide red (E172), magnesium stearate (E572)

What Rizatriptan Tablets looks like and contents of the pack

Rizatriptan 5 mg Tablets are pale pink colored, capsule shaped tablet debossed with 'HP' on one side and "244" on other side

Rizatriptan 10 mg Tablets are pale pink colored, capsule shaped tablet debossed with 'HP' on one side and "245" on other side

Rizatriptan 5mg Tablets are supplied in unit dose blisters consisting of Aluminium forming (OPA/Alu/PVC) and Aluminium lidding (PAP/PET/AL) containing 3, 6 and 18 tablets.

Rizatriptan 10 mg Tablets are supplied in unit dose blisters consisting of Aluminium forming (OPA/Alu/PVC) and Aluminium lidding (PAP/PET/AL) containing 3, 6, 12 and 18 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Tillomed Laboratories Ltd
220 Butterfield, Great Marlings
Luton, LU2 8DL
United Kingdom

Manufacturer

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