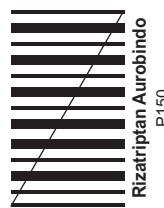


Pharmacode position may change as per Supplier's m/c requirement & additional small pharma code may appear on the front / back panel



Package leaflet: Information for the user

Rizatriptan 5 mg tablets Rizatriptan 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 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
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 and alcohol

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 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 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 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 lactose:

Rizatriptan contains lactose monohydrate, a type of sugar. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

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 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 up to a maximum of 2 doses in a 24-hour period.

Rizatriptan (rizatriptan benzoate) tablets should be taken by mouth and swallowed whole with liquid.

Rizatriptan is also available as a 10-mg wafer (referred to technically as an oral lyophilisate) that dissolves in the mouth. The wafer 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. 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 or 5 mg tablets or 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 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 over-dosage 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.

The following side effects may happen with this medicine.

In adult studies, the most common side effects reported were dizziness, sleepiness and tiredness.

Common (affects 1 to 10 users in 100)

- tingling (paraesthesia), headache, decreased sensitivity of skin (hypoesthesia), decreased mental sharpness, tremor,
- fast or irregular heart beat (palpitation), very fast heartbeat (tachycardia),
- flushing (redness of the face lasting a short time), hot flushes, sweating,
- throat discomfort, difficulty breathing (dyspnoea),
- feeling sick (nausea), dry mouth, vomiting, diarrhoea,
- feeling of heaviness in parts of the body,
- 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,
- confusion, insomnia, nervousness,
- high blood pressure (hypertension); thirst, indigestion (dyspepsia),
- rash, itching and lumpy rash (hives), swelling of face, lips, tongue and/or throat which may cause difficulty breathing and/or swallowing (angioedema)
- neck pain, feeling of tightness in parts of the body, stiffness, 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).
- facial pain; muscle pain.

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

- fainting (syncope)
- wheezing
- allergic reaction (hypersensitivity); sudden life-threatening allergic reaction (anaphylaxis);
- stroke (this 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]).
- 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Malta

ADR Reporting
Website:
www.medicinesauthority.gov.mt

e-mail:
postlicensing.medicinesauthority@gov.mt

The United Kingdom

Yellow Card Scheme
Website:

www.mhra.gov.uk/yellowcard

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 blister and carton after EXP. The expiry date refers to the last day of that 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 contains

- The active substance is rizatriptan.
Each tablet contains 7.265 mg of rizatriptan benzoate equivalent to 5 mg of rizatriptan.
Each tablet contains 14.530 mg of rizatriptan benzoate equivalent to 10 mg of rizatriptan.
- The other ingredients are:
Cellulose, Microcrystalline, lactose monohydrate (see section 2), maize starch, ferric oxide red, starch pregelatinized magnesium stearate.

What Rizatriptan looks like and contents of pack

Tablets

Rizatriptan 5 mg tablets:

Pale pink coloured, circular, flat, beveled edge uncoated tablets debossed with 'X' on one side and '13' on other side. The tablets may be mottled.

Rizatriptan 10 mg tablets:

Pale pink coloured, circular, flat, beveled edge uncoated tablets debossed with 'X' on one side and '14' on other side. The tablets may be mottled.

Rizatriptan tablets are available in Polyamide/ Aluminium / PVC - Aluminium foil blister packs of: 1, 2, 3, 6, 12 and 18 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

UK_ Milpharm Limited
Ares Block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

MT_ Aurobindo Pharma (Malta) Limited
Vault 14, Level 2, Valletta Waterfront
Floriana FRN 1913
Malta

Manufacturer

APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far
Birzebbugia, BBG 3000
Malta

or

Milpharm Limited
Ares Block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark	Rizatriptan "Aurobindo"
France	Rizatriptan Aurobindo 5 mg/10 mg comprimé
Germany	Rizatriptan Aurobindo 5 mg/10 mg Tabletten
Malta	Rizatriptan 5 mg/10 mg tablets
Netherlands	Rizatriptan Aurobindo 5 mg/10 mg tabletten
Spain	Rizatriptán Aurobindo 10 mg comprimidos
Sweden	Rizatriptan Aurobindo 5 mg/10 mg tabletter
United Kingdom	Rizatriptan 5 mg/10 mg tablets

This leaflet was last revised in 06/2014