Package leaflet: Information for the user

Rizatriptan 5 mg orodispersible tablets
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, evenif 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 effectsnot 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-HT1B/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 insection 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 attackyou 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 applies 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 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 5HT1B/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

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.

Available data on the safety of rizatriptan when used during the first 3 months of pregnancy do not suggest an increased risk of birth defects. It is not known whether Rizatriptan is harmful to an unborn baby when taken by a pregnant woman after the first 3 months of pregnancy.

If you are breastfeeding, you may postpone breastfeeding for 12 hours after treatment to avoid exposure in your baby.

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

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.

Rizatriptan contains Aspartame

Rizatriptan contains aspartame, a source of phenylalanine. This may be harmfulfor 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 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.

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 least2 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 morethan two 10-mg or 5 mg orodispersible tablets or tablets in a 24-hour period). You should alwayswait at least 2 hours between doses.

If your condition worsens, seek medical attention.

How to administer Rizatriptan orodispersible tablets

- Rizatriptan orodispersible tablets dissolves in the mouth.
- Open the blister pack with dry hands.
- The orodispersible tablets 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.

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

If you take more Rizatriptan than you should

If you take more Rizatriptan than you should, talk to your doctor or pharmacistraight 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 (may affect up to 1 in 10 people)

- tingling (paraesthesia), headache, decreased sensitivity of skin (hypoaesthesia), 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 (may affect up to 1 in 100 people)

- 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 (may affect up to 1 in 1,000 people)

- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard, or search 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 blister, carton and bottle label after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original package in order to protect from light and moisture.

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.

  Rizatriptan 5 mg orodispersible tablets:
  Each tablet contains 7.265 mg of rizatriptan benzoate equivalent to 5 mg of rizatriptan.

  Rizatriptan 10 mg orodispersible tablets:
  Each tablet contains 14.530 mg of rizatriptan benzoate equivalent to 10 mg of rizatriptan.

- The other ingredients are:
  Lactose monohydrate, microcrystalline cellulose (E 460a), calcium silicate (E 552), crospovidone (E 1202), aspartame (E 951), peppermint flavour (maize maltodextrin and modified waxy maize starch (E 1450), anhydrous colloidal silica (E 511) and magnesium stearate (E 470b).

What Rizatriptan looks like and contents of pack

Orodispersible tablets

Rizatriptan 5 mg orodispersible tablets:
White to off-white coloured, round flat bevelled tablets with a diameter of 9.0 mm

Rizatriptan 10 mg orodispersible tablets:
White to off-white coloured, round flat bevelled tablets with a diameter of 10.5 mm.

Rizatriptan orodispersible tablets are available in peel-off aluminium/aluminium blister packs of 2, 3, 6, 12 and 18 tablets.

Not all pack sizes may be marketed.

Marketing Authorization Holder

Neuraxpharm UK Limited
First Floor, Building 1410,
Arlington Business Park,
Theale, Reading,
Berkshire RG7 4SA

Manufacturer

Neuraxpharm Pharmaceuticals, S.L.
Avda. Barcelona, 69
08970 Sant Joan Despi
Barcelona - Spain

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