PACKAGE LEAFLET

Package leaflet: Information for the user

RIZADIA 5 mg oral lyophilisate
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 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 RIZADIA is and what it is used for

RIZADIA belongs to a class of medicines called selective serotonin 5-$HT_{1B/1D}$ receptor agonists.

RIZADIA is used to treat the headache phase of a migraine attack in adults.

Treatment with RIZADIA:
Reduces the 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 RIZADIA

Do not take RIZADIA 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 **Other medicines and RIZADIA** below)

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking RIZADIA.

Warnings and precautions
Talk to your doctor or pharmacist before taking RIZADIA, 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
- have kidney or liver problems
- have a particular problem with the way your heart beats (bundle branch block)
- have or have had any allergies
- experience dizziness, difficulty in walking, lack of coordination or weakness in the legs and arms at the same time as your headache
- use a herbal preparation containing St. John's wort
- have ever had an allergic reaction like swelling of the face, lips, tongue and/or throat which may cause difficulty breathing and/or swallowing (angioedema)
- are taking medications for depression called selective serotonin reuptake inhibitors (SSRIs) such as sertraline, escitalopram oxalate, and fluoxetine or serotonin norepinephrine reuptake inhibitors (SNRIs) such as venlafaxine, and duloxetine
- have had temporary symptoms including chest pain and tightness

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

Other medicines and RIZADIA

Do not take RIZADIA if you
- are already taking a 5-$HT_{1B/1D}$ agonist (sometimes referred to as 'triptans'), such as sumatriptan, naratriptan or zolmitriptan
- 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 last took an MAO inhibitor
- use ergotamine-type medications such as ergotamine or dihydro-ergotamine to treat your migraine
- use methysergide to prevent a migraine attack

The above listed medicines, when taken with RIZADIA, may increase the risk of side effects.

You should wait at least 6 hours after taking RIZADIA 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 RIZADIA.

Ask your doctor for instructions and the risks about taking RIZADIA if you:
- are taking propranolol (see section 3: **How to take RIZADIA**)
- are taking SSRIs such as sertraline, escitalopram oxalate, and fluoxetine or SNRIs such as venlafaxine, and duloxetine for depression

Tell your doctor or pharmacist if you are taking, 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 RIZADIA can affect the way some medicines work. Also, other medicines can affect RIZADIA.

RIZADIA with food and drink

RIZADIA 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.

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 RIZADIA 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 breast-feeding for 12 hours after treatment to avoid exposure in your baby.

Children and adolescents

The use of RIZADIA oral lyophilisate for 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 RIZADIA is amongst patients older than 65 years.

Driving or using machines

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

RIZADIA contains aspartame
This medicine contains 1.88 mg aspartame in each 5 mg oral lyophilisate which is equivalent to 1.1 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 RIZADIA

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

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

The usual dose is two oral lyophilisates (10 mg).

If you are currently taking propranolol or have kidney or liver problems, you should use 1 oral lyophilisate (5 mg). You should leave at least 2 hours between taking propranolol and RIZADIA 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 RIZADIA. You should always wait at least 2 hours between doses. **Do not take more than 2 doses of RIZADIA in a 24-hour period, (for example, if you are on a 10mg dose, do not take more than four 5-mg oral lyophilisates in a 24-hour period).**

If after 2 hours you still have a migraine
If you do not respond to the first dose of RIZADIA during an attack, you should not take a second dose of RIZADIA for treatment of the same attack. It is still likely, however, that you will respond to RIZADIA during the next attack.

If your condition worsens, seek medical attention.

How to administer RIZADIA oral lyophilisate

- RIZADIA (rizatriptan benzoate) is available as a 5 mg oral lyophilisate that dissolves in the mouth.
- Open the 'RIZADIA' oral lyophilisate blister pack with dry hands.
- The oral lyophilisate should be placed on your tongue, where it dissolves and can be swallowed with the saliva.
- The oral lyophilisate can be used when liquids are not available, or to avoid the nausea and vomiting that may accompany swallowing tablets with liquids.

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

If you take more RIZADIA than you should:

If you take more RIZADIA 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 product 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 (hypoaesthesia), decreased mental sharpness, insomnia
- fast or irregular heart-beat (palpitations)
- flushing (temporary redness of the face)
- 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) such as itching, wheezing, hives, rash, and severe sloughing of the skin; sudden life-threatening allergic reaction (anaphylaxis) including swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing and/or swallowing
- stroke (this generally occurs in patients with risk factors for heart and blood vessel disease (high blood pressure, diabetes, smoking, use of nicotine substitutes, family history of heart disease or stroke, men 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 substitutes, family history of heart disease or stroke, men 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)
- blood vessel spasm of the extremities including coldness and numbness of the hands or feet
- blood vessel spasm of the colon (large bowel), which can cause abdominal pain

Tell your doctor right away if you have the 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 RIZADIA.

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 HPRA Pharmcovigilance, website: www.HPRA.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store RIZADIA

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.

Do not store RIZADIA oral lyophilisate above 30°C.

Store in the original packaging in order to protect from moisture.

Do not remove the oral lyophilisate blister from the outer aluminium sachet until you are ready to take the medicine inside. Do not use the medicine if you notice that the aluminium sachet is damaged.

Always keep the aluminium sachets in the carrying case.

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 RIZADIA contains

RIZADIA 5 mg oral lyophilisate
The active substance of RIZADIA is rizatriptan. One oral lyophilisate contains 5 mg rizatriptan as 7.265 mg of rizatriptan benzoate.

The other ingredients of RIZADIA oral lyophilisate are: gelatin, mannitol (E421), glycine, aspartame (E951), and peppermint flavour (composed of peppermint oil, maltodextrin, and dextrin).

What RIZADIA looks like and contents of pack

RIZADIA 5 mg oral lyophilisate
5 mg oral lyophilisate are white to off-white, round with a modified triangle on one side, with a peppermint flavour.

Pack size: packs with 2 oral lyophilisates

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Organon Pharma (Ireland) Limited
2 Dublin Landings
North Wall Quay – North Dock
Dublin, D01 V4A3
Ireland

Manufacturer

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2031 BN Haarlem
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Kloosterstraat 6
5349 AB Oss
The Netherlands

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

Germany	Maxalt Migräne 5 mg Schmelztabletten
Ireland	RIZADIA 5 mg oral lyophilisate

This leaflet was last revised in June 2025 .