

RIZATRIPTAN-AU Orodispersible tablets

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using RIZATRIPTAN-AU?

RIZATRIPTAN-AU contains the active ingredient Rizatriptan benzoate. RIZATRIPTAN-AU is used to relieve the headache pain and other symptoms of migraine attacks.

For more information, see Section [1. Why am I using RIZATRIPTAN-AU?](#) in the full CMI.

2. What should I know before I use RIZATRIPTAN-AU?

Do not use if you have ever had an allergic reaction to Rizatriptan benzoate or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use RIZATRIPTAN-AU?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with RIZATRIPTAN-AU and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use RIZATRIPTAN-AU?

- Take RIZATRIPTAN-AU only when prescribed by your doctor.
- The usual dose to treat a migraine is one 10 mg orodispersible tablet before or after food.

More instructions can be found in Section [4. How do I use RIZATRIPTAN-AU?](#) in the full CMI.

5. What should I know while using RIZATRIPTAN-AU?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Rizatriptan-AU for migraines.• If your headache is more severe than your 'usual' migraine or it behaves differently, tell your doctor.• If you become pregnant while taking RIZATRIPTAN-AU, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">• Do not give RIZATRIPTAN-AU to anyone else, even if they have the same condition as you.• You should not take RIZATRIPTAN-AU 10mg while you are taking propranolol.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how RIZATRIPTAN-AU affect you.• Migraine or treatment with RIZATRIPTAN-AU may cause sleepiness or dizziness in some people.
Drinking alcohol	<ul style="list-style-type: none">• If you drink alcohol, sleepiness or dizziness may be worse.
Looking after your medicine	<ul style="list-style-type: none">• Store below 30°C.

For more information, see Section [5. What should I know while using RIZATRIPTAN-AU?](#) in the full CMI.

6. Are there any side effects?

RIZATRIPTAN-AU help most people with migraine headaches, but they may have unwanted side effects in a few people such as Dizziness, sleepiness and tiredness, Abnormalities of the electrocardiogram, heart attack, angina and stroke etc.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

RIZATRIPTAN-AU Orodispersible tablets

Active ingredient(s): *Rizatriptan benzoate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using RIZATRIPTAN-AU. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using RIZATRIPTAN-AU.**

Where to find information in this leaflet:

- [1. Why am I using RIZATRIPTAN-AU?](#)
- [2. What should I know before I use RIZATRIPTAN-AU?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use RIZATRIPTAN-AU?](#)
- [5. What should I know while using RIZATRIPTAN-AU?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using RIZATRIPTAN-AU?

RIZATRIPTAN-AU contains the active ingredient **Rizatriptan benzoate**. RIZATRIPTAN-AU is used to relieve the headache pain and other symptoms of migraine attacks. RIZATRIPTAN-AU do not work for other types of headaches.

During a migraine attack, blood vessels in the brain dilate, or widen, resulting in a throbbing pain.

RIZATRIPTAN-AU decrease this widening, returning the blood vessels to their normal size, and therefore helps to relieve the pain.

RIZATRIPTAN-AU also block the release of certain chemicals from nerve endings that cause more pain and other symptoms of migraine.

Migraine is an intense, throbbing, typically one-sided headache. It often includes nausea, vomiting, sensitivity to light, and sensitivity to sound. Some people may have visual symptoms before the headache, called an aura. An aura can include flashing lights or wavy lines.

Migraine attacks last anything from two hours to two days and they can return frequently. The severity and frequency of migraine attacks may vary.

Migraine occurs in about one out of every 10 people. It is three times more common in women than men.

Six out of ten migraine sufferers have their first attack before the age of 20.

There is no single cause of migraine. It tends to run in families. Certain things, singly or in combination, can trigger migraine attacks in some people. Some of these triggers are:

- certain foods or drinks, for example, cheese and other dairy products, chocolate, citrus fruit, caffeine, alcohol (especially red wine)
- stress, anger, worry
- changes in routine, for example, under or over sleeping, missing a meal, change in diet
- bright light or loud noises
- hormonal changes in women, for example, during menstrual periods

If you understand what triggers your attacks, you may be able to prevent migraine attacks or reduce their frequency. Keeping a headache diary will help you identify and monitor all of the possible migraine triggers you encounter. Once the triggers are identified, you and your doctor can modify your treatment and lifestyle appropriately.

Ask your doctor if you have any questions about why RIZATRIPTAN-AU has been prescribed for you.

2. What should I know before I use RIZATRIPTAN-AU?

Warnings

Do not use RIZATRIPTAN-AU if:

- you are allergic to Rizatriptan benzoate, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you are currently taking monoamine oxidase inhibitors (MAOIs) for depression, or have taken them within the last two weeks.
MAOIs include moclobemide, phenelzine, tranylcypromine and pargyline.
- the packaging is torn or shows signs of tampering.
- the expiry date on the pack has passed. If you take this medicine after the expiry date has passed, it may not work.
- you are not sure whether you should start taking RIZATRIPTAN-AU, talk to your doctor.

Check with your doctor if you:

- have any other medical conditions or have any risks factors for heart or blood vessel disease, including:
 - high blood pressure
 - diabetes
 - smoking
 - a high cholesterol level
 - a family history of heart or blood vessel disease
- your headache is more severe than your 'usual' migraine, or it behaves differently
- have a condition called phenylketonuria

The 5mg orodispersible tablet contains 4.4mg phenylalanine (a component of aspartame) and the 10mg orodispersible tablet contains 8.8mg phenylalanine.

- take any medicines for any other condition
 - have, have had, any other medical conditions such as
 - high blood pressure that is not being treated
 - some heart diseases, including angina, or a previous heart attack
 - a stroke or transient ischaemic attack (TIA)
 - blood vessel problems, including ischaemic bowel disease
- have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell them before you take any RIZATRIPTAN-AU.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Like most medicines, RIZATRIPTANAU are not recommended for use during pregnancy. If there is a need to consider RIZATRIPTAN-AU during pregnancy, your doctor will discuss with you the risks and benefits of taking them during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known whether RIZATRIPTAN-AU pass into breast milk. Your doctor will discuss with you the risks and benefits of taking them while breast-feeding.

Children (<18 years)

Do not give RIZATRIPTAN-AU to children under 18 years of age.

The safety and effectiveness of RIZATRIPTAN-AU in children under 18 years have not been established.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines should not be taken with RIZATRIPTAN-AU. These include:

- monoamine oxidase inhibitors (MAOIs) used to treat depression, including moclobemide, tranylcypromine, phenelzine, pargyline
- sumatriptan, another similar medicine used to treat migraine

Some medicines, herbal products, or dietary supplements, and RIZATRIPTAN-AU may interfere with each other and affects how well it works. These include:

- propranolol, a medicine used to treat high blood
- ergotamine, dihydroergotamine, other medicines used to treat migraine
- methysergide, a medicine used to prevent migraine
- St. John's wort (*Hypericum perforatum*), a herbal product sold as a dietary supplement, or products containing St. John's wort

You may need different amounts of your medicine, you may need to take different medicines or you may need to be careful of the timing of some of these medicines.

Ask your doctor for instructions about taking RIZATRIPTAN-AU if you are also 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.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking RIZATRIPTAN-AU.

4. How do I use RIZATRIPTAN-AU?

How much to take

- The usual dose to treat a migraine is one 10 mg orodispersible tablet.
- If the first RIZATRIPTAN-AU orodispersible tablet does help your migraine, but it comes back later, you may take another orodispersible tablet.
- Take the second orodispersible tablet at least 2 hours after the first. Do not take more than 30 mg (three 10 mg orodispersible tablets) in a 24 hour period.
- If the first RIZATRIPTAN-AU orodispersible tablet does not help your migraine, do not take another orodispersible tablet for the same attack as it is unlikely to help. It is still likely, however, that you will respond to RIZATRIPTAN-AU during your next attack.
- Follow the instructions provided to you by your doctor carefully. They may differ from the information contained in this leaflet and use RIZATRIPTAN-AU until your doctor tells you to stop. **If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

When to take / use RIZATRIPTAN-AU

- Take RIZATRIPTAN-AU only when prescribed by your doctor.
- It does not matter if you take RIZATRIPTAN-AU before or after food.

How to take RIZATRIPTAN-AU

- **Do not to remove the orodispersible tablet from the blister until just prior to dosing.**

- With dry hands push the orodispersible tablet through the foil and place the orodispersible tablet on your tongue.
- The orodispersible tablet will dissolve rapidly and be swallowed with your saliva. No water is needed for taking the orodispersible tablet.

If you forget to use RIZATRIPTAN-AU

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much RIZATRIPTAN-AU

If you think that you have used too much RIZATRIPTAN-AU, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you take too many orodispersible tablets, you may feel sleepy, dizzy, faint or have a slow heart beat.

5. What should I know while using RIZATRIPTAN-AU?

Things you should do

Call your doctor straight away if you:

- your headache is more severe than your 'usual' migraine or it behaves differently
- are about to be started on any new medicine, tell your doctor and pharmacist that you take RIZATRIPTAN-AU for migraines.
- become pregnant while taking RIZATRIPTAN-AU, tell your doctor immediately.

Remind any doctor, dentist or pharmacist you visit that you are using RIZATRIPTAN-AU.

Things you should not do

- Do not give RIZATRIPTAN-AU to anyone else, even if they have the same condition as you.
- You should not take RIZATRIPTAN-AU 10mg while you are taking propranolol.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how RIZATRIPTAN-AU affects you.

Migraine or treatment with RIZATRIPTAN-AU may cause dizziness in some people. Make sure you know how you react to RIZATRIPTAN-AU before you drive a car, operate machinery, or do anything else that could be dangerous if you are sleepy or dizzy.

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol, sleepiness or dizziness may be worse.

Looking after your medicine

- Store below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

RIZATRIPTAN-AU help most people with migraine headaches, but they may have unwanted side effects in a few people. All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>1. difficulty thinking or working because of:</p> <ul style="list-style-type: none"> • sleepiness, tiredness • dizziness • inability to sleep • decreased mental sharpness • nervousness • agitation • seeing/ feeling/ hearing things that are not there • headache not relieved by RIZATRIPTAN-AU <p>2. stomach or bowel problems</p> <ul style="list-style-type: none"> • feeling sick (nausea), vomiting • stomach upset or pain • diarrhoea <p>3. changes in your sight or taste such as:</p> <ul style="list-style-type: none"> • blurred vision 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> • dry mouth • thirst • bad taste • throat discomfort • tongue swelling <p>4. skin problems</p> <ul style="list-style-type: none"> • skin rash, itching • redness or flushing of the face • hot flushes, sweating <p>5. changes in the way your body feels, such as:</p> <ul style="list-style-type: none"> • feelings of heaviness or tightness on parts of the body • muscle weakness • muscle pain • tingling or numbness of the hands or feet • tremor, unsteadiness when walking • spinning sensation, also called vertigo • very high temperature • unusually increased reflexes or lack of coordination <p>6. fast, slow or irregular heart beats, palpitations</p> <p>7. neck pain or facial pain</p>	
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Dizziness, sleepiness and tiredness are the most common side effects of RIZATRIPTAN-AU. For the most part, these have been mild.

Abnormalities of the electrocardiogram (a test that records the electrical activity of your heart) have also been reported.

If you take RIZATRIPTAN-AU too often, you may get chronic headaches. Contact your doctor as you may have to stop taking RIZATRIPTAN-AU.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • fainting, coma • pinkish, itchy swellings on the skin, also called hives or nettle rash • swelling of the face, lips, mouth, tongue or throat which may cause • difficulty in swallowing or breathing • shortness of breath, wheezing • pain or tightness in chest (which may be symptoms of heart attack or angina) • collapse, numbness or weakness of the arms or legs, headache, dizziness and confusion, visual disturbance, difficulty swallowing, slurred speech and loss of speech (which may be symptoms of stroke) • severe skin reaction which starts 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

<p>with painful red areas, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell.</p> <ul style="list-style-type: none"> • seizures, fits or convulsions • persistent purple discolouration, and/or pain in the fingers, toes, ears, nose or jaw • pain or spasms in the lower stomach, bloody diarrhoea and fever 	
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Serious side effects are rare.

As with other medicines in the same class as RIZATRIPTAN-AU, heart attack, angina and stroke have been reported very rarely, and generally occurred in people with risk factors for heart or blood vessel disease (including high blood pressure, diabetes, smoking, family history of heart or blood vessel disease e.g. stroke).

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What RIZATRIPTAN-AU contains

Active ingredient (main ingredient)	Rizatriptan (as benzoate) 5mg* - 7.265mg rizatriptan benzoate per wafer, equivalent to 5 mg rizatriptan 10mg - 14.53mg rizatriptan benzoate per wafer, equivalent to 10mg rizatriptan
Other ingredients (inactive ingredients)	Mannitol, microcrystalline cellulose, calcium silicate, crospovidone, aspartame, colloidal anhydrous silica, Mint Extra Spray Dried Flavour

	1207342 (PI 148208) and magnesium stearate.
Potential allergens	None

Do not take this medicine if you are allergic to any of these ingredients.

What RIZATRIPTAN-AU looks like

RIZATRIPTAN-AU Orodispersible tablets are available in two strengths:

5mg# - White, round, flat, bevel-edged tablet embossed with "IZ 5" on one side and plain on the other side.

A blister pack contains 2, 3# or 6# orodispersible tablets. (AUST R 220023)

10mg - White, round, flat, bevel-edged tablet embossed with "IZ 10" on one side and plain on the other side.

A pack contains 2, 3# or 6# orodispersible tablets. (AUST R 220028)

Not currently marketed.

Who distributes RIZATRIPTAN-AU

Marketed and Distributed by Medsurge Healthcare Pty Ltd.

Telephone: 1300 788 261

Website: www.medsurgehc.com

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