

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 RIXALT?

RIXALT contains the active ingredient rizatriptan benzoate. RIXALT is used to relieve the headache pain and other symptoms of migraine attacks.

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

2. What should I know before I use RIXALT?

Do not use if you have ever had an allergic reaction to RIXALT 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 RIXALT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with RIXALT 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 RIXALT?

- Take Rixalt only when prescribed by your doctor
- The usual dose to treat a migraine is one 10 mg orally disintegrating tablet
- If the first RIXALT orally disintegrating tablet does help your migraine, but it comes back later, you may take another orally disintegrating tablet. **Take the second orally disintegrating tablet at least 2 hours after the first.**

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

5. What should I know while using RIXALT?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using RIXALT.• If your headache is more severe than your 'usual' migraine or it behaves differently, tell your doctor• If you become pregnant while taking RIXALT, tell your doctor immediately
Things you should not do	<ul style="list-style-type: none">• Do not give RIXALT to anyone else, even if they have the same condition as you
Driving or using machines	<ul style="list-style-type: none">• Before you drive a car, operate machinery or do anything else that could be dangerous if you are sleepy or dizzy, be careful as RIXALT 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 in a cool dry place where the temperature stays below 30°C

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

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). The most common side effects include dizziness, somnolence and weakness/fatigue. If you experience swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, tell your doctor immediately or go to accident and emergency at your nearest hospital.

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.

RIXALT

Active ingredient: *rizatriptan (as benzoate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using RIXALT. **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 RIXALT.**

Where to find information in this leaflet:

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

1. Why am I using RIXALT?

RIXALT contains the active ingredient rizatriptan.

Rizatriptan is a serotonergic agonist. During a migraine attack, blood vessels in the brain dilate, or widen, resulting in a throbbing pain. Rizatriptan decreases this widening, returning the blood vessels to their normal size, and therefore helps to relieve the pain. It also blocks the release of certain chemicals from nerve endings that cause more pain and other symptoms of migraine.

RIXALT is used to relieve the headache pain and other symptoms of migraine attacks. RIXALT does not work for other types of headaches.

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. 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.

2. What should I know before I use RIXALT?

Warnings

Do not use RIXALT if:

- you are allergic to rizatriptan, 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 have high blood pressure that is not being treated
- you have heart disease (including angina or a previous heart attack)

- you have or have had a stroke or transient ischaemic attack (TIA)
- you have blood vessel problems, including ischaemic bowel disease
- you are currently taking monoamine oxidase inhibitors (MAOIs) for depression or have taken them within the last two weeks
- the packaging is torn or shows signs of tampering
- the expiry date on the pack has passed

Do not give RIXALT to children under 18 years of age.

Check with your doctor if you:

- have, or have had, any other medical conditions
- take any medicines for any other condition
- you have any risks factors for heart or blood vessel disease, including high blood pressure, diabetes, smoking, a high cholesterol level and/or a family history of heart or blood vessel disease
- you are not sure whether you should start taking RIXALT
- your headache is more severe than your 'usual' migraine, and/or it behaves differently
- you have a condition called phenylketonuria as the tablets contain phenylamine (a component of aspartame)
- you 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 RIXALT.

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, RIXALT is not recommended for use during pregnancy. If there is a need to consider RIXALT 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 RIXALT passes into breast milk. Your doctor will discuss with you the risks and benefits of taking them while breast-feeding.

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 RIXALT. These include:

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

Ask your doctor for instructions about taking RIXALT if you are also taking:

- selective serotonin reuptake inhibitors (SSRIs) such as sertraline, escitalopram oxalate or fluoxetine
- serotonin norepinephrine reuptake inhibitors (SNRIs) such as venlafaxine and duloxetine for depression

Some medicines, herbal products or dietary supplements, and RIXALT may interfere with each other. These include:

- propranolol (a medicine used to treat high blood pressure)
- ergotamine, dihydroergotamine or 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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect RIXALT.

4. How do I use RIXALT?

How much to take / use

- Take only when prescribed by your doctor
- The usual dose to treat a migraine is one 10 mg orally disintegrating tablet

Do not remove the orally disintegrating tablet from the blister until just prior to dosing. With dry hands push the orally disintegrating tablet through the foil and place the orally disintegrating tablet on your tongue.

The orally disintegrating tablet will dissolve rapidly and be swallowed with your saliva. No water is needed for taking the orally disintegrating tablet.

It does not matter if you take RIXALT before or after food.

Follow the instructions provided and use RIXALT until your doctor tells you to stop.

When to take / use RIXALT

- RIXALT should be used when you suffer a migraine attack
- If the first RIXALT orally disintegrating tablet does help your migraine, but it comes back later, you may take another orally disintegrating tablet
- **Take the second orally disintegrating tablet at least 2 hours after the first.** Do not take more than 30 mg (three 10 mg orally disintegrating tablets) in a 24 hour period.
- If the first RIXALT orally disintegrating tablet does not help your migraine, do not take another orally disintegrating tablet for the same attack as it is unlikely to help. It is still likely, however, that you will respond to RIXALT during your next attack.

If you forget to use RIXALT

- RIXALT should be used when you suffer a migraine attack
- If required only take a second tablet at least two hours after taking the first tablet

If you use too much RIXALT

If you think that you have used too much RIXALT, 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.

5. What should I know while using RIXALT?

Things you should do

If your headache is more severe than your 'usual' migraine or it behaves differently, tell your doctor.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you take RIXALT for migraines.

If you become pregnant while taking RIXALT, tell your doctor immediately.

Call your doctor straight away if you:

- do not feel well while you are taking RIXALT

Remind any doctor, dentist or pharmacist you visit that you are using RIXALT.

Things you should not do

- Do not give RIXALT to anyone else, even if they have the same condition as you

Driving or using machines

Be careful before you drive or use any machines or tools until you know how RIXALT affects you.

RIXALT may cause sleepiness or dizziness in some people. Make sure you know how you react to RIXALT 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.

Alcohol may cause sleepiness or dizziness to be worse.

Looking after your medicine

- Keep RIXALT in a cool dry place where the temperature stays below 30°C

Follow the instructions on 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.

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?

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

Dizziness, sleepiness and tiredness are the most common side effects of RIXALT. For the most part, these have been mild.

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 RIXALT <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• 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>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

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

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

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">fainting, comapinkish, itchy swellings on the skin, also called hives or nettle rashswelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathingshortness of breath, wheezingpain 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 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.seizures, fits or convulsionspersistent purple discolouration, and/or pain in the fingers, toes, ears, nose or jawpain or spasms in the lower stomach, bloody diarrhoea and fever	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.

As with other medicines in the same class as RIXALT, 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 such as 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.

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 RIXALT contains

Active ingredient (main ingredient)	Rizatriptan (as benzoate)
Other ingredients (inactive ingredients)	mannitol microcrystalline cellulose calcium silicate crospovidone aspartame magnesium stearate silica colloidal anhydrous Mint Extra Spray Dried Flavour 1207342 (PI 148208)
Potential allergens	aspartame

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

What RIXALT looks like

RIXALT (AUST R 220024) is a white, round, flat, bevel-edged tablet engraved with "IZ 10" on one side and plain on the other side.

A pack contains 2 orally disintegrating tablets.

Who distributes RIXALT

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel St

Cremorne 3121 VIC Australia

www.arrotex.com.au

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