

# RIXALT orally disintegrating tablets

Rizatriptan benzoate

## Consumer Medicine Information

### What is in this leaflet

Please read this leaflet carefully before you start using RIXALT. This leaflet answers some common questions about RIXALT. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking RIXALT against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

### What RIXALT is used for

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

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 RIXALT has been prescribed for you.

### How RIXALT works

During a migraine attack, blood vessels in the brain dilate, or widen, resulting in a throbbing pain. RIXALT decreases this widening, returning the blood vessels to their normal size, and therefore helps to relieve

the pain. RIXALT also blocks the release of certain chemicals from nerve endings that cause more pain and other symptoms of migraine.

### Before you take RIXALT

#### When you must not use it

**Do not take RIXALT if you have an allergy to RIXALT or any of the ingredients listed at the end of this leaflet.**

**Do not take RIXALT if you have or had:**

- 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

**Do not take RIXALT if 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.

**Do not take RIXALT if the packaging is torn or shows signs of tampering.**

**Do not take RIXALT if the expiry date on the pack has passed.**

If you take this medicine after the expiry date has passed, it may not work.

**If you are not sure whether you should start taking RIXALT, talk to your doctor.**

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

The safety and effectiveness of RIXALT in children under 18 years have not been established.

#### Before you start to take it

**Tell your doctor if:**

1. **you are pregnant or intend to become pregnant**

Like most medicines, RIXALT are 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.

2. **you are breast-feeding or plan to breast-feed**

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

3. **you 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

4. **your headache is more severe than your 'usual' migraine, or it behaves differently**

5. **you have a condition called phenylketonuria**

The 5mg orally disintegrating tablet contains 4.4mg phenylalanine (a

component of aspartame) and the 10mg orally disintegrating tablet contains 8.8mg phenylalanine.

6. **you have, or have had, any other medical conditions**

7. **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.**

#### Taking other medicines

**Tell your doctor if you are taking any other medicines, herbal products, or dietary supplements, including those 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

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, 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

These medicines, herbal products, or dietary supplements may be affected by RIXALT, or may affect how well it works. 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 RIXALT 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 RIXALT.

### How to take RIXALT

#### How much to take

**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. 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.

**You should not take RIXALT 10mg while you are taking propranolol.**

**Follow all directions given to you by your doctor carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

*How to take it*

**Do not to 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.

*If you take too much (overdose)*

**Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too many RIXALT. Do this even if there are no signs of discomfort or poisoning.**

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

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## While you are using RIXALT

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*Things you must 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.**

*Things you must not do*

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

*Things to be careful of*

**Be careful driving or operating machinery until you know how RIXALT affect you.**

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

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking RIXALT.**

RIXALT help most people with migraine headaches, but they may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not.

You may need medical treatment if you get some of the side effects.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor if you notice any of the following and they worry you:**

**1. difficulty thinking or working because of:**

- sleepiness, tiredness
- dizziness
- inability to sleep
- decreased mental sharpness
- nervousness
- agitation
- seeing/ feeling/ hearing things that are not there
- headache not relieved by RIXALT

**2. stomach or bowel problems**

- feeling sick (nausea), vomiting
- stomach upset or pain
- diarrhoea

**3. changes in your sight or taste such as:**

- blurred vision
- dry mouth
- thirst
- bad taste
- throat discomfort
- tongue swelling

**4. skin problems**

- skin rash, itching
- redness or flushing of the face
- hot flushes, sweating

**5. changes in the way your body feels, such as:**

- 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

**6. fast, slow or irregular heart beats, palpitations**

**7. neck pain or facial pain**

Dizziness, sleepiness and tiredness are the most common side effects of RIXALT. 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 RIXALT too often, you may get chronic headaches. Contact your doctor as you may have to stop taking RIXALT.

**Tell your doctor immediately or go to accident and emergency at your nearest hospital if you notice any of the following:**

- 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 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 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

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

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 e.g. stroke).

**Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.**

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

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## After using RIXALT

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*Storage*

**Keep RIXALT in a cool dry place where the temperature stays below 30°C. Do not store them or any other medicine in the bathroom or near a sink.**

**Do not leave them in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep them where children cannot reach them.**

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

*Disposal*

If your doctor tells you to stop taking the orally disintegrating tablets, or the orally disintegrating tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

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## Product description

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*What it looks like*

RIXALT orally disintegrating tablets are available in two strengths:

RIXALT orally disintegrating tablets 5mg\* - White, round, flat, bevel-edged tablet embossed with "IZ 5" on one side and plain on the other side.

A pack contains 2, 3 or 6 orally disintegrating tablets\*.

RIXALT orally disintegrating tablets 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\* orally  
disintegrating tablets.

### ***Ingredients***

Active ingredient:

- RIXALT orally disintegrating tablets  
5mg\* - 7.265mg rizatriptan benzoate per  
wafer, equivalent to 5 mg rizatriptan
- RIXALT orally disintegrating tablets  
10mg - 14.53mg rizatriptan benzoate per  
wafer, equivalent to 10mg rizatriptan

Inactive ingredients:

- Mannitol
- microcrystalline cellulose
- calcium silicate
- crospovidone
- aspartame
- silica colloidal anhydrous
- peppermint flavour
- magnesium stearate

RIXALT orally disintegrating tablets do not  
contain gluten, lactose, sucrose, tartrazine or  
any other azo dyes. This medicine contains  
aspartame.

### ***Supplier***

RIXALT orally disintegrating tablets are  
supplied in Australia by:

Arrotex Pharmaceuticals Pty Ltd  
15-17 Chapel St  
Cremorne VIC 3121

This leaflet was prepared in September 2023.

Australian Register Number:

5 mg - AUST R 220034\*

10 mg - AUST R 220024

\* Not currently marketed.