

# RIZATRIPTAN-AU Orodispersible tablets

Rizatriptan benzoate

## Consumer Medicine Information

### What is in this leaflet

Please read this leaflet carefully before you start using RIZATRIPTAN-AU. This leaflet answers some common questions about RIZATRIPTAN-AU. 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 RIZATRIPTAN-AU 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 RIZATRIPTAN-AU Are used for

RIZATRIPTAN-AU are used to relieve the headache pain and other symptoms of migraine attacks. RIZATRIPTAN-AU do 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 RIZATRIPTAN-AU has been prescribed for you.

### How RIZATRIPTAN-AU work

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.

### Before you take RIZATRIPTAN-AU

#### When you must not use it

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

**Do not take RIZATRIPTAN-AU 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 RIZATRIPTAN-AU 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 RIZATRIPTAN-AU if the packaging is torn or shows signs of tampering.**

**Do not take RIZATRIPTAN-AU 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 RIZATRIPTAN-AU, talk to your doctor.**

**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.

#### Before you start to take it

**Tell your doctor if:**

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

Like most medicines, RIZATRIPTAN-AU 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.

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

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.

**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 orodispersible tablet contains 4.4mg phenylalanine (a component of aspartame) and the 10mg orodispersible 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 RIZATRIPTAN-AU.**

#### 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 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. 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 RIZATRIPTAN-AU, 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 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.

### How to take RIZATRIPTAN-AU

#### How much to take

**Take RIZATRIPTAN-AU only when prescribed by your doctor.**

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.

**You should not take RIZATRIPTAN-AU 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 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.

It does not matter if you take RIZATRIPTAN-AU 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 RIZATRIPTAN-AU. 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.

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**While you are using RIZATRIPTAN-AU**

*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 RIZATRIPTAN-AU for migraines.**

**If you become pregnant while taking RIZATRIPTAN-AU, tell your doctor immediately.**

*Things you must not do*

**Do not give RIZATRIPTAN-AU 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 RIZATRIPTAN-AU affect you.**

Migraine or treatment with RIZATRIPTAN-AU may cause sleepiness or 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. If you drink alcohol, sleepiness or dizziness may be worse.

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## Side effects

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

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. 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 RIZATRIPTAN-AU

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 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.

**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 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).

**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 RIZATRIPTAN-AU

### Storage

**Keep RIZATRIPTAN-AU 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 orodispersible tablets, or the orodispersible 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*

RIZATRIPTAN-AU Orodispersible tablets are available in two strengths:

RIZATRIPTAN-AU Orodispersible 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 orodispersible tablets\*.

RIZATRIPTAN-AU Orodispersible 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\* orodispersible tablets.

### **Ingredients**

Active ingredient:

- RIZATRIPTAN-AU Orodispersible tablets 5mg\* - 7.265mg rizatriptan benzoate per wafer, equivalent to 5 mg rizatriptan
- RIZATRIPTAN-AU Orodispersible 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

RIZATRIPTAN-AU Orodispersible tablets do not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

### **Supplier**

RIZATRIPTAN-AU Orodispersible tablets are supplied in Australia by:

Medsurge Healthcare Pty Limited  
Unit 2, 6-7 Gilda Court  
MULGRAVE VICTORIA 3170

This leaflet was prepared in June 2020.

Australian Register Number:

5 mg - AUST R 220023\*

10 mg - AUST R 220028

\* Not currently marketed.