

Rizatriptan AN ODT orally disintegrating tablets

Rizatriptan benzoate

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using Rizatriptan AN ODT. This leaflet answers some common questions about Rizatriptan AN ODT. 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 AN ODT 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 AN ODT is used for

Rizatriptan AN ODT is used to relieve the headache pain and other symptoms of migraine attacks. Rizatriptan AN ODT 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 Rizatriptan AN ODT has been prescribed for you.

How Rizatriptan AN ODT works

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

Before you take Rizatriptan AN ODT

When you must not use it

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

Do not take Rizatriptan AN ODT 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 AN ODT 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 AN ODT if the packaging is torn or shows signs of tampering.

Do not take Rizatriptan AN ODT 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 AN ODT, talk to your doctor.

Do not give Rizatriptan AN ODT to children under 18 years of age.

The safety and effectiveness of Rizatriptan AN ODT 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 AN ODT are not recommended for use during pregnancy. If there is a need to consider Rizatriptan AN ODT 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 AN ODT 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 Rizatriptan AN ODT.

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 AN ODT.

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 AN ODT 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 AN ODT, 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 AN ODT 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 AN ODT.

How to take Rizatriptan AN ODT

How much to take

Take Rizatriptan AN ODT only when prescribed by your doctor.

The usual dose to treat a migraine is one 10 mg orally disintegrating tablet.

If the first Rizatriptan AN ODT 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 Rizatriptan AN ODT 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 Rizatriptan AN ODT during your next attack.

You should not take Rizatriptan AN ODT 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 Rizatriptan AN ODT 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 AN ODT. 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.

While you are using Rizatriptan AN ODT

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 AN ODT for migraines.

If you become pregnant while taking Rizatriptan AN ODT, tell your doctor immediately.

Things you must not do

Do not give Rizatriptan AN ODT 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 AN ODT affect you.

Migraine or treatment with Rizatriptan AN ODT may cause sleepiness or dizziness in some people. Make sure you know how you react to Rizatriptan AN ODT 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Rizatriptan AN ODT.

Rizatriptan AN ODT 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 AN ODT**

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 AN ODT. 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 AN ODT too often, you may get chronic headaches. Contact your doctor as you may have to stop taking Rizatriptan AN ODT.

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 nettlerash
- 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 AN ODT, 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.

After using Rizatriptan AN ODT

Storage

Keep Rizatriptan AN ODT 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.

Product description

What it looks like

Rizatriptan AN ODT orally disintegrating tablets are available in two strengths:

Rizatriptan AN ODT 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*.

Rizatriptan AN ODT 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:

- Rizatriptan AN ODT orally disintegrating tablets 5mg* - 7.265mg rizatriptan benzoate per wafer, equivalent to 5 mg rizatriptan
- Rizatriptan AN ODT 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

Rizatriptan AN ODT orally disintegrating tablets do not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Supplier

Rizatriptan AN ODT orally disintegrating tablets are supplied in Australia by:

Amneal Pharma Australia Pty Ltd
12 River Street
South Yarra VIC 3141

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Australian Register Number:

5 mg - AUST R 220034*

10 mg - AUST R 220024

* Not currently marketed.