

APO-Rizatriptan Orally Disintegrating Tablets

Contains the active ingredient Rizatriptan benzoate

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about Rizatriptan Orally Disintegrating Tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Rizatriptan Orally Disintegrating Tablets. It contains the active ingredient rizatriptan benzoate.

It is used to relieve the headache pain and other symptoms of migraine attacks.

Rizatriptan Orally Disintegrating Tablets 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 every 10 people. It is three times more common in women than men.

Six out of ten migraine sufferers 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, 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 meal, change in diet
- Bright light or loud noises
- Hormonal changes in women, 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 of the possible migraine triggers 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 this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

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

How it works

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. Rizatriptan also blocks the release of certain chemicals from nerve endings that

cause more pain and other symptoms of migraine.

There is no evidence that this medicine is addictive

Use in children

This medicine should not be used in children.

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

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have or have had any of the following:**
- **Concurrent administration of monoamine oxidase inhibitors (MAOIs) for depression, or use within 2 weeks of discontinuation of MAOIs therapy. MAOIs include moclobemide, phenelzine, tranylcypromine and pargyline.**
- **Uncontrolled hypertension**
- **Established coronary artery disease, including ischemic heart disease (angina pectoris, history of myocardial infarction, or documented silent ischemia), signs and symptoms of ischemic heart disease, or Prinzmetal's angina**
- **History of stroke or transient ischemic attack (TIA)**
- **Peripheral vascular disease, including (but not limited to) ischemic bowel disease**
- **You are hypersensitive to, or have had an allergic reaction to, rizatriptan or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives

on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.
- If you are not sure whether you should start taking rizatriptan, talk to your doctor.
- Do not give rizatriptan to children under 18 years of age.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant. Like most medicines, rizatriptan is not recommended for use during pregnancy. If there is need to consider rizatriptan during pregnancy, your doctor will discuss with you the risks and benefits of taking them during pregnancy
4. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding. It is not known whether rizatriptan pass into breast milk. Your doctor will discuss with you the risks and benefits of taking them while breast-feeding.

5. 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
6. Your headache is more severe than your 'usual' migraine, or it behaves differently
7. You have, or have had, any other medical conditions
8. You are planning to have surgery or an anaesthetic.
9. You are currently receiving or are planning to receive dental treatment.
10. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines should not be taken with rizatriptan. 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 may interact with rizatriptan. 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, or may affect how well it works. If you are taking any

of these you may need a different dose or 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 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.

Other medicines not listed above may also interact with rizatriptan.

Your doctor has more information on medicines to be careful with or avoid while taking rizatriptan.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

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

If the first rizatriptan tablet does help your migraine, but it comes back later, you may take another tablet.

Take the second tablet at least 2 hours after the first. Do not take more than 30 mg (three 10 mg tablets) in a 24 hour period.

If the first rizatriptan tablet does not help your migraine, do not take another tablet for the same attack as it is unlikely to help. It is still likely, however, that you will respond to rizatriptan during your next attack.

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

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

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

With dry hands place the tablet on your tongue.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

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

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

While you are taking this medicine

Things you must do

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

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

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

rizatriptan 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.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking rizatriptan or if you have any questions or concerns.

Rizatriptan helps most people with migraine headaches, but they may have unwanted side effects in a few people. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

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
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 heartbeats, palpitations
 7. neck pain or facial pain

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

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are serious side effects and you may need urgent medical attention or hospitalisation. Serious side effects are rare:

- 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

As with other medicines in the same class as rizatriptan, 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.

Allergic reactions

If you think you are having an allergic reaction to rizatriptan, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing

- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

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 this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Rizatriptan orally disintegrating tablets look like

Rizatriptan orally disintegrating tablets are available in two strengths:

5mg: White to off-white coloured, round-shaped tablets with "APO" engraved on one side and "RZ" over "5" on the other side.

Blister Pack of 2 tablets.

10mg: White to off-white coloured, round-shaped tablets with "APO" engraved on one side and "RZ" over "10" on the other side.

Blister Pack of 2 tablets.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains rizatriptan benzoate (equivalent to 5 mg or 10 mg of rizatriptan, respectively).

It also contains the following inactive ingredients:

- Cellulose-microcrystalline
- Mannitol
- Crospovidone
- Sucralose
- Magnesium stearate
- Peppermint flavour.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Rizatriptan 5mg orally disintegrating tablets (blister pack):
AUST R 222327

APO-Rizatriptan 10mg orally disintegrating tablets (blister pack):
AUST R 222334

Sponsor

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