

APO-RIZATRIPTAN ODT tablets

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 this medicine?

APO-RIZATRIPTAN ODT contains the active ingredient rizatriptan benzoate. APO-RIZATRIPTAN ODT is used to relieve the headache pain and other symptoms of acute migraine attacks.

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

2. What should I know before I use this medicine?

Do not use if you have ever had an allergic reaction to APO-RIZATRIPTAN ODT or any 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 this medicine?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-RIZATRIPTAN ODT 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 this medicine?

- Take APO-RIZATRIPTAN ODT tablets only when prescribed by your doctor.
- The usual dose to treat a migraine is one 10 mg tablet
- If the first APO-RIZATRIPTAN ODT 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 24 hour period.

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

5. What should I know while using this medicine?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using APO-RIZATRIPTAN ODT .• If your headache is more severe or behaves differently to your usual 'migraine' tell your doctor or pharmacist• If you become pregnant while taking APO-RIZATRIPTAN ODT tell your doctor immediately
Things you should not do	<ul style="list-style-type: none">• Do not give APO-RIZATRIPTAN ODT to anyone else, even if they have the same condition as you
Driving or using machines	<ul style="list-style-type: none">• APO-RIZATRIPTAN ODT may cause sleepiness or dizziness in some people. Make sure you know how you react to APO-RIZATRIPTAN ODT before you drive a car or operate machinery.
Drinking alcohol	<ul style="list-style-type: none">• If you drink alcohol, sleepiness or dizziness associated with migraine or treatment with APO-RIZATRIPTAN ODT may be worse.
Looking after your medicine	<ul style="list-style-type: none">• Keep APO-RIZATRIPTAN ODT in a cool dry place where the temperature stays below 30°C.• Keep the blister containing each individual tablet in the aluminum sachet until it is time to take it.

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

6. Are there any side effects?

The Common side effects are dizziness, sleepiness and tiredness. As with other medicines in the same class as APO-RIZATRIPTAN 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.

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.

APO-RIZATRIPTAN ODT tablets

Active ingredient(s): rizatriptan benzoate

Consumer Medicine Information (CMI)

This leaflet provides important information about using this medicine. **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 this medicine.**

Where to find information in this leaflet:

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

1. Why am I using this medicine?

APO-RIZATRIPTAN ODT contains the active ingredient rizatriptan benzoate. APO-RIZATRIPTAN ODT belongs to a class of drugs called serotonin agonists.

APO-RIZATRIPTAN ODT is used for the acute relief of migraine in patients. APO-RIZATRIPTAN ODT is used to relieve the headache pain and other symptoms of migraine attacks.

Do not use APO-RIZATRIPTAN ODT unless your condition has been diagnosed by a doctor.

APO-RIZATRIPTAN ODT does not work in other types of headaches which are not migraine.

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.

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

Ask your doctor or pharmacist if you have any questions about APO-RIZATRIPTAN ODT.

2. What should I know before I use this medicine?

Warnings

Do not use APO-RIZATRIPTAN ODT if:

- you are allergic to rizatriptan benzoate, 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 or have 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
- you are currently taking monoamine oxidase inhibitors (MAOIs) for depression or have taken them within the last 2 weeks.**
MAOIs include moclobemide, phenelzine, tranylcypromine and pargyline.
- you are currently taking any of these medicines:
 - ergotamine
 - dihydroergotamine
 - methysergide
 - other triptans i.e., sumatriptan, eletriptan, naratriptan, zolmitriptan
- the packaging is torn or shows signs of tampering**

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

If you are not sure whether you should start taking APO-RIZATRIPTAN ODT, talk to your doctor or pharmacist.

Check with your doctor if you:

- **you are pregnant or intend to become pregnant or breast-feeding (See section 'Pregnancy and Breastfeeding' below)**
- **you have any risk 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

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

- **you have a condition called phenylketonuria**

The 5 mg tablet contains 1.05 mg phenylalanine (a component of aspartame) and the 10 mg tablet contains 2.10 mg phenylalanine.

- you have, or have had any other medical conditions
- you have allergies to any other medicines or any other substances, such as foods, preservatives or dyes
- take any medicines for any other condition.

If you have not told your doctor or pharmacist about any of the above, tell them before you take any APO-RIZATRIPTAN ODT.

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 or pharmacist if you are pregnant or intend to become pregnant.

Like most medicines, APO-RIZATRIPTAN ODT is not recommended for use during pregnancy. If there is a need to consider APO-RIZATRIPTAN ODT during pregnancy, your doctor or pharmacist will discuss with you the risks and benefits of taking them during pregnancy.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

It is not known whether APO-RIZATRIPTAN ODT passes into breast milk. Your doctor or pharmacist will discuss with you the risks and benefits of taking them while breastfeeding.

Use in Children and Adolescents (under 18 years)

Do not give APO-RIZATRIPTAN ODT to children under 18 years of age.

The safety and effectiveness of APO-RIZATRIPTAN ODT in children under 18 years have not been established.

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 APO-RIZATRIPTAN ODT. These include:

- monoamine oxidase inhibitors (MAOIs) used to treat depression, including moclobemide, tranylcypromine, phenelzine, pargyline
- other medicines used to treat migraine

Some medicines, herbal products, or dietary supplements, and APO-RIZATRIPTAN 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 APO-RIZATRIPTAN 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 or pharmacist for instructions about taking APO-RIZATRIPTAN 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 APO-RIZATRIPTAN ODT.

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

4. How do I use this medicine?

How much to take

- Take APO-RIZATRIPTAN ODT only if your condition has been diagnosed by your doctor.
- The usual dose to relieve a migraine is one 10 mg tablet.
- If the first dose does help your migraine but it comes back later, you may take another 10 mg dose.
- Take the second dose 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 APO-RIZATRIPTAN ODT 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 APO-RIZATRIPTAN ODT during your next attack.
- You should not take a dose of 10 mg while you are taking propranolol.
- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.

When to take APO-RIZATRIPTAN ODT

APO-RIZATRIPTAN ODT should be used:

- when the migraine headache begins; or
- when other symptoms of the migraine begin, such as nausea (feeling sick), vomiting or your eyes become sensitive to light.

Do not take APO-RIZATRIPTAN ODT before the above symptoms occur.

How to take APO-RIZATRIPTAN ODT

Remove the blister containing each individual tablet from the outer sachet when it is time to take it.

The blister pack should then be peeled open with dry hands and the tablet placed on your tongue, where it will dissolve and be swallowed with your saliva. No water is needed for taking the tablet.

It does not matter if you take APO-RIZATRIPTAN ODT before or after food.

If you use too much APO-RIZATRIPTAN ODT

If you think that you have used too much APO-RIZATRIPTAN ODT, 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.

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

5. What should I know while using this medicine?

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 APO-RIZATRIPTAN ODT for migraines.
- If you become pregnant while taking APO-RIZATRIPTAN ODT, tell your doctor immediately.
- Remind any doctor, dentist or pharmacist you visit that you are using APO-RIZATRIPTAN ODT.

Things you should not do

- Do not give APO-RIZATRIPTAN ODT to anyone else, even if they have the same condition as you.

Medication overuse headaches

Overuse of migraine medications, such as rizatriptan, have been associated with worsening of headaches (medication overuse headache or MOH) in some patients.

Overuse of medications for relief of headache and migraine can worsen your condition and lead to:

- Increase of headache frequency, and
- Can make your condition less responsive to treatments

If you are experiencing frequent or daily headaches, it is possible that you may be experiencing medication overuse headache. If your migraines have become more frequent, you should speak with your doctor or pharmacist.

Driving or using machines

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

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

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

Looking after your medicine

- Keep your medicine in the pack until it is time to take it.
- If you take your medicine out of the pack it may not keep well.
- **Keep APO-RIZATRIPTAN ODT in a cool dry place where the temperature stays below 30°C.**

Follow the instructions in the carton on how to take care of your medicine properly.

Heat and dampness can destroy some medicines. 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 below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • dizziness • inability to sleep • decreased mental sharpness • nervousness • agitation • seeing/ feeling/ hearing things that are not there • headache not relieved by APO-RIZATRIPTAN ODT <p>Stomach or bowel problems</p> <ul style="list-style-type: none"> • feeling sick (nausea), vomiting • stomach upset or pain • diarrhoea <p>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>Skin problems</p> <ul style="list-style-type: none"> • skin rash, itching • redness or flushing of the face • hot flushes, sweating <p>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 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • spinning sensation, also called vertigo • very high temperature • unusually increased reflexes or lack of coordination <p>Fast, slow or irregular heartbeats, palpitations</p> <ul style="list-style-type: none"> • Abnormalities of the electrocardiogram (a test that records the electrical activity of your heart) have also been reported • Neck pain or facial pain 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Dizziness, sleepiness and tiredness are the most common side effects of APO-RIZATRIPTAN ODT . For the most part, these have been mild.

If you take APO-RIZATRIPTAN ODT too often, you may get chronic headaches. Contact your doctor as you may have to stop taking APO-RIZATRIPTAN ODT .

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • These are serious side effects. You may need urgent medical attention. Serious side effects are rare. • 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 attach 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 	<p>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.</p>

fever	
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As with other medicines in the same class as APO-RIZATRIPTAN 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).

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, can be reported 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 this medicine contains

Active ingredient (main ingredient)	Each tablet contains rizatriptan benzoate (equivalent to 10 mg of rizatriptan).
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• mannitol• calcium silicate• microcrystalline cellulose• crospovidone• aspartame• magnesium stearate• colloidal anhydrous silica• Mint Extra Spray Dried Flavour 1207342 (PI 148208).
Potential allergens	contains aspartame

This medicine does not contain gluten, lactose, sucrose, tartrazine and other azo dyes.

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

What this medicine looks like

10mg: White, round, flat, bevel-edged tablet engraved with "IZ 10" on one side and plain on the other side.

Blister pack of 2 tablets.

AUST R 220030.

Who distributes this medicine

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street,

Cremorne, VIC 3121

www.arrotex.com.au

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