MAXALT® MIGRAINE RELIEF

Active ingredient: rizatriptan benzoate

Consumer Medicine Information (CMI)

This leaflet provides important information about using MAXALT MIGRAINE RELIEF. 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 MAXALT MIGRAINE RELIEF.

Where to find information in this leaflet:

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- 2. What should I know before I use MAXALT MIGRAINE RELIEF?
- 3. What if I am taking other medicines?
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1. Why am I using MAXALT MIGRAINE RELIEF?

MAXALT MIGRAINE RELIEF contains the active ingredient rizatriptan benzoate. MAXALT MIGRAINE RELIEF belongs to a class of drugs called serotonin agonists.

MAXALT MIGRAINE RELIEF is used for the acute relief of migraine in patients who have a stable, well-established pattern of symptoms. They should not be used to prevent migraine attacks from occurring. Do not use MAXALT MIGRAINE RELIEF unless your condition has been diagnosed by a doctor.

MAXALT MIGRAINE RELIEF 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 or pharmacist can modify your treatment and lifestyle appropriately.

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

2. What should I know before I use MAXALT MIGRAINE RELIEF?

Warnings

Do not use MAXALT MIGRAINE RELIEF 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
 - o 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
 - o dihydroergotamine
 - o methysergide
 - o sumatriptan
 - o eletriptan
 - o naratriptan
 - o 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 MAXALT MIGRAINE RELIEF, talk to your doctor or pharmacist.

Check with your doctor or pharmacist if:

- you have any risk factors for heart or blood vessel disease, including:
 - o high blood pressure
 - o diabetes
 - o smoking
 - o a high cholesterol level
 - a family history of heart or blood vessel disease

- o obesity
- o are a male and over 40 years of age
- o are female and have undergone menopause
- your headache is more severe than your 'usual' migraine, or it behaves differently
- you have a condition called phenylketonuria
- The 5 mg wafer contains 1.05 mg phenylalanine (a component of aspartame)
- 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 MAXALT MIGRAINE RELIEF.

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, MAXALT MIGRAINE RELIEF is not recommended for use during pregnancy. If there is a need to consider MAXALT MIGRAINE RELIEF 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 MAXALT MIGRAINE RELIEF passes into breast milk. Your doctor or pharmacist will discuss with you the risks and benefits of taking them while breast-feeding

Use in Children and Adolescents (under 18 years)

Do not give MAXALT MIRGRAINE RELIEF to children under 18 years of age.

The safety and effectiveness of MAXALT MIGRAINE RELIEF 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 MAXALT MIGRAINE RELIEF. These include:

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

Some medicines, herbal products, or dietary supplements, and MAXALT MIGRAINE RELIEF 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 MAXALT MIGRAINE RELIEF, 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 MAXALT MIGRAINE RELIEF 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 MAXALT MIGRAINE RELIEF.

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

4. How do I use MAXALT MIGRAINE RELIEF?

How much to take

- Take MAXALT MIGRAINE RELIEF only if your condition has been diagnosed by your doctor.
- The usual adult dose (18 years and over) to relieve a migraine is 10 mg, or two 5 mg wafers.
- If the first dose does help your migraine but it comes back within 24 hours, talk to your doctor or pharmacist
- You should not take a dose of 10 mg (two 5 mg wafers) while you are taking propranolol.
- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.

When to take it

MAXALT MIGRAINE RELIEF 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 MAXALT MIGRAINE RELIEF before the above symptoms occur.

How to take it

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

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

It does not matter if you take MAXALT MIGRAINE RELIEF before or after food.

If you use too much MAXALT MIGRAINE RELIEF

If you think that you have used too much MAXALT MIGRAINE RELIEF, 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.

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You should do this even if there are no signs of discomfort or poisoning.

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

5. What should I know while using MAXALT MIGRAINE RELIEF?

Things you should do

- If your headache is more severe than your 'usual' migraine or it behaves differently, tell your doctor or pharmacist.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you take MAXALT MIGRAINE RELIEF for migraines.
- If you become pregnant while taking MAXALT MIGRAINE RELIEF, tell your doctor immediately.
- Remind any doctor, dentist or pharmacist you visit that you are using MAXALT MIGRAINE RELIEF

Things you should not do

 Do not give MAXALT MIGRAINE RELIEF 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 MAXALT MIGRAINE RELIEF affects you.

Migraine or treatment with MAXALT MIGRAINE RELIEF may cause sleepiness or dizziness in some people. Make sure you know how you react to MAXALT MIGRAINE RELIEF 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 or pharmacist if you drink alcohol.

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

Looking after your medicine

- Keep your blister containing each individual wafer in the aluminium sachet until it is time to take it.
- Each wafer is packed in a blister within an outer aluminium sachet. If you take the wafer out of the blister and PVC/PVDC/Al sachet, it may not keep well.
- Keep MAXALT MIGRAINE RELIEF 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.

Less serious side effects

Less serious side effects	What to do
difficulty thinking or working because of:	Speak to your doctor or
 sleepiness, tiredness dizziness inability to sleep decreased mental sharpness nervousness agitation seeing/ feeling/ hearing things that are not there headache not relieved by MAXALT MIGRAINE RELIEF 	pharmacist if you have any of these less serious side effects and they worry you.
Dizziness, sleepiness and tiredness are the most common side effects of MAXALT MIGRAINE RELIEF. For the most part, these have been mild.	
If you take MAXALT MIGRAINE RELIEF too often, you may get chronic headaches. Contact your doctor as you may have to stop taking MAXALT MIGRAINE RELIEF.	
stomach or bowel problems	
feeling sick (nausea), vomitingstomach upset or paindiarrhoea	
changes in your sight or taste such as:	
 blurred vision dry mouth thirst bad taste throat discomfort tongue swelling 	
skin problems	
 skin rash, itching redness or flushing of the face hot flushes, sweating 	

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Less serious side effects	What to do
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 	
fast, slow or irregular heart beats, palpitations	
Abnormalities of the electrocardiogram (a test that records the electrical activity of your heart) have also been reported	
neck pain or facial pain	

Serious side effects

Serious side effects	What to do
As with other medicines in the same class as MAXALT MIGRAINE RELIEF, 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, you can report side effects 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.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What MAXALT MIGRAINE RELIEF contains

Active ingredient (main ingredient)	7.265 mg rizatriptan benzoate per wafer, equivalent to 5 mg of rizatriptan
Other ingredients (inactive ingredients)	gelatin mannitol
ingredients)	glycine aspartame Peppermint NAEFCO P0551
	957685 (ARTG ID: 2890)
Potential allergens	Phenylketonurics are warned that this product contains aspartame (phenylalanine)

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

What MAXALT MIGRAINE RELIEF looks like

MAXALT MIGRAINE RELIEF – a white to off-white round wafer with a flat or slightly irregular surface. (Aust R 407853).

A pack contains 2 wafers

Who distributes MAXALT MIGRAINE RELIEF

Organon Pharma Pty Ltd

Building A, 26 Talavera Road

Macquarie Park NSW 2113

This leaflet was prepared in April 2023.

This CMI leaflet was current at the time of printing. To check if it has been updated, please visit our website, www.organon.com/Australia, or ask your pharmacist.

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