

MAXALT® Wafers

Rizatriptan benzoate

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using MAXALT Wafers. This leaflet answers some common questions about MAXALT Wafers. 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 MAXALT Wafers 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 MAXALT Wafers are used for

MAXALT Wafers are used to relieve the headache pain and other symptoms of migraine attacks. MAXALT Wafers 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 MAXALT has been prescribed for you.

How MAXALT Wafers work

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

Before you take MAXALT Wafers

When you must not take it

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

Do not take MAXALT Wafers 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 MAXALT Wafers 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 MAXALT Wafers if the packaging is torn or shows signs of tampering.

Do not take MAXALT Wafers 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 MAXALT Wafers, talk to your doctor.

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

The safety and effectiveness of MAXALT Wafers 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, MAXALT Wafers are not recommended for use during pregnancy. If there is a need to consider MAXALT Wafers 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 MAXALT Wafers 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 wafer* contains 1.05mg phenylalanine (a

component of aspartame) and the 10mg wafer contains 2.10mg 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 MAXALT Wafers.

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 MAXALT Wafers.

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 MAXALT Wafers 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 Wafers, 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 MAXALT Wafers 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 Wafers.

How to take MAXALT Wafers

How much to take

Take MAXALT Wafers only when prescribed by your doctor.

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

If the first MAXALT Wafer does help your migraine, but it comes back later, you may take another wafer.

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

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

You should not take MAXALT 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

With dry hands place the wafer on your tongue.

The wafer will dissolve rapidly and be swallowed with your saliva. No water is needed for taking the wafer.

It does not matter if you take MAXALT Wafers 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 MAXALT Wafers. 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.

While you are using MAXALT Wafers

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 MAXALT Wafers for migraines.

If you become pregnant while taking MAXALT Wafers, tell your doctor immediately.

Things you must not do

Do not give MAXALT Wafers 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 MAXALT Wafers affect you.

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

MAXALT Wafers 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 MAXALT
- 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 MAXALT Wafers. 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 MAXALT Wafers too often, you may get chronic headaches. Contact your doctor as you may have to stop taking MAXALT Wafers.

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 MAXALT, 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 MAXALT Wafers

Storage

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 Wafers 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 wafers, or the wafers have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

MAXALT Wafers are available in two strengths:

MAXALT Wafers 5mg* - a white to off-white round wafer with a flat or slightly irregular surface.

A pack contains 2, 3 or 6 wafers*.

MAXALT Wafers 10mg - a white to off-white round wafer with a flat or slightly irregular surface.

A pack contains 2, 3 or 6 wafers. A starter pack containing 1 MAXALT 10 mg wafer is also available.

Ingredients

Active ingredient:

- MAXALT Wafers 5mg* - 7.265mg rizatriptan benzoate per wafer, equivalent to 5 mg rizatriptan
- MAXALT Wafers 10mg - 14.53mg rizatriptan benzoate per wafer, equivalent to 10mg rizatriptan

Inactive ingredients:

- gelatin
- mannitol
- glycine
- aspartame
- proprietary ingredient peppermint flavour (ARTG ID: 2890)

MAXALT Wafers do not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Supplier

MAXALT Wafers are supplied in Australia by:

Merck Sharp & Dohme (Australia) Pty Limited
Level 1, Building A
26 Talavera Road
Macquarie Park NSW 2113

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

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5 mg - AUST R 69077*
10 mg - AUST R 69076

* Not currently marketed in Australia.

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