

# MAXALT<sup>®</sup>

*rizatriptan benzoate*

5 mg wafer (Not currently marketed in New Zealand)

# MAXALT<sup>®</sup> MELT

*rizatriptan benzoate*

10 mg wafer

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## What is in this leaflet

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Please read this leaflet carefully before you start using MAXALT/MAXALT MELT (wafers). This leaflet answers some common questions about MAXALT/MAXALT MELT. 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/MAXALT MELT 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.

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## What MAXALT/MAXALT MELT is used for

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MAXALT/MAXALT MELT is used to relieve the headache pain and other symptoms of migraine attacks. MAXALT/MAXALT MELT 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 MAXALT/MAXALT MELT has been prescribed for you.

### **How MAXALT/MAXALT MELT works**

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

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## **Before you take MAXALT/MAXALT MELT**

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### ***When you must not take it***

Do not take MAXALT/MAXALT MELT if:

- **you have an allergy to MAXALT/MAXALT MELT or any of the ingredients listed at the end of this leaflet**
- **you have high blood pressure that is not being treated**
- **you have some heart diseases, including angina, or a previous heart attack**
- **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.
- **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 date has passed, it may not work.

**If you are not sure whether you should start taking MAXALT/MAXALT MELT, talk to your doctor.**

**Do not give MAXALT/MAXALT MELT to children under 18 years of age.** The safety and effectiveness of MAXALT/MAXALT MELT 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/MAXALT MELT is not recommended for use during pregnancy. If there is a need to consider MAXALT/MAXALT MELT during pregnancy, your doctor will discuss with you the risks and benefits of taking it during pregnancy.

#### **2. you are breast-feeding or plan to breast-feed**

It is not known whether MAXALT/MAXALT MELT passes into breast milk. Your doctor will discuss with you the risks and benefits of taking it while breast-feeding.

**3. 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

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

**5. you have a condition called phenylketonuria**

Each 5 mg MAXALT wafer\* contains 1.05 mg phenylalanine (a component of aspartame), and each 10 mg MAXALT Melt wafer contains 2.10 mg 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/MAXALT MELT.**

### ***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/MAXALT MELT.

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 and MAXALT/MAXALT MELT 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

These medicines may be affected by MAXALT/MAXALT MELT, 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/MAXALT MELT 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/MAXALT MELT.

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## How to take MAXALT/MAXALT MELT

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### *How much to take*

Take MAXALT/MAXALT MELT only when prescribed by your doctor.

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

If the first MAXALT MELT 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 MELT 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 MELT during your next attack.

**You should not take MAXALT MELT 10 mg 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/MAXALT MELT before or after food.

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## While you are using MAXALT/MAXALT MELT

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### *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/MAXALT MELT for migraines.**

**If you become pregnant while taking MAXALT/MAXALT MELT, tell your doctor immediately.**

### *Things you must not do*

Do not give MAXALT/MAXALT MELT 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/MAXALT MELT affects you.**

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

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## **In case of overdose**

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### ***If you take too much (overdose)***

**Immediately telephone your doctor or Poisons Information Centre (in Australia, telephone 13 11 26; in New Zealand, telephone 0800 POISON or 0800 764 766) for advice, or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much MAXALT/MAXALT MELT.**

**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.

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## **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking MAXALT/MAXALT MELT.**

MAXALT/MAXALT MELT helps most people with migraine headaches, but it may have unwanted adverse effects in a few people. All medicines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse 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/MAXALT MELT

### **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/MAXALT MELT. 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.

***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 and/or throat which may cause difficulty in breathing and/or swallowing
- 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 adverse effects. You may need urgent medical attention. Serious adverse effects are rare.

As with other medicines in this class, there have been very rare reports of heart attack and stroke generally occurring in patients who are at risk of heart and blood vessel disease (high blood pressure, diabetes, smoking, family history of heart or blood vessel disease e.g. stroke).

**Other adverse 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 adverse effects. You may not experience any of them.

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## After using MAXALT/MAXALT MELT

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### ***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 aluminium sachet, it may not keep well.

**Keep MAXALT/MAXALT MELT in a cool dry place. Store at room temperature, 15-30°C (59-86°F). Do not store it or any other medicine in the bathroom or near a sink.**

**Do not leave it in the car or on window sills.**

Heat and dampness can destroy some medicines.

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

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## Product description

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### ***What it looks like***

- MAXALT 5 mg\* – is a white to off-white round wafer with a flat or a slightly irregular surface debossed on one side with a modified triangle and plain on the other.
- MAXALT MELT 10 mg – is a white to off-white round wafer with a flat or slightly irregular surface debossed on one side with a modified square and plain on the other. MAXALT MELT 10 mg packs contain 3 wafers.

## ***Ingredients***

### **Active ingredient:**

- MAXALT 5 mg\* – 7.265 mg rizatriptan benzoate per wafer, equivalent to 5 mg rizatriptan
- MAXALT MELT 10 mg – 14.53 mg rizatriptan benzoate per wafer, equivalent to 10 mg rizatriptan

### **Inactive ingredients:**

- gelatin
- mannitol
- glycine
- aspartame
- peppermint flavour

MAXALT/MAXALT MELT does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

\* Not currently marketed in New Zealand.

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## **Sponsor details**

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MAXALT/MAXALT MELT is supplied in New Zealand by:

Merck Sharp & Dohme (New Zealand) Limited

P O Box 99 851

Newmarket

Auckland

NEW ZEALAND

Telephone: 0800 500 673

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## **Date of preparation**

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This leaflet was prepared on 14 February 2012.

MAXALT Wafer NZ-CMI A120214 v4

Based on MAXALT Wafer DS A111221 v4 (WPC-MK0462-T-R-082011)

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