

NEW ZEALAND CONSUMER MEDICINE INFORMATION

RIZAMELT

Rizatriptan benzoate orodispersible tablets 5 mg & 10 mg



What is in this leaflet

This leaflet answers some common questions about RIZAMELT.

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 RIZAMELT 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 RIZAMELT is used for

RIZAMELT is used to treat headache pain and other symptoms associated with migraine attacks. It does not work for other types of headaches.

A 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.

RIZAMELT contains the active ingredient rizatriptan benzoate. It belongs to a group of medicines called 5-HT_{1BD/1D} receptor agonists (also known as serotonin receptor agonists).

RIZAMELT is an orodispersible tablet. This means the tablet is designed to dissolve on the tongue, in the mouth, and that patients do not require a drink to swallow the tablet with.

A migraine attack is caused by the blood vessels in the brain widening/dilating which results in the throbbing, painful headache.

RIZAMELT works by reducing the dilated blood vessels in the brain to their normal size and therefore helps to relieve the pain. It also blocks the release of certain chemicals from nerve endings that cause more pain and other symptoms of migraine.

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, e.g. under or over sleeping, change in diet, missing meals
- bright light or loud noises

- hormonal changes in women, e.g. 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 this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

Before you take RIZAMELT

When you must not take it:

Do not take RIZAMELT if :

- You have an allergy to any medicine containing rizatriptan benzoate or any of the ingredients listed at the end of this leaflet
- You are currently taking a monoamine oxidase inhibitor medicine (MAOI), or have used a MAOI in the last two weeks
- You have high blood pressure that is not being treated
- You have a heart disease or a heart condition including angina or have had a previous heart attack

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or

difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine if you are pregnant unless you discuss the risks and benefits with your doctor first. It has not been adequately studied for use in pregnancy.

Do not breast-feed if you are taking this medicine.

It is not known whether rizatriptan, the active ingredient in RIZAMELT passes into breast milk.

Do not give this medicine to children under the age of 18 years.

Safety and effectiveness of RIZAMELT in children under 18 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it:

Tell your doctor if:

- You have allergies to any other medicines, foods, preservatives or dyes
- You are pregnant or you are planning to become pregnant
- You are breastfeeding or plan to breastfeed
- Your headache is more severe than your "usual" migraine, or it behaves differently
- You have basilar migraines or hemiplegic migraines
- You have any other medical conditions.

Tell your doctor if you have or have had any of the following medical conditions:

- High blood pressure
- Diabetes

- Smoking
- A high cholesterol level
- A family history of heart disease

Tell your doctor if you suffer from Phenylketonuria (PKU) as RIZAMELT contains phenylalanine which is a component of aspartame.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking RIZAMELT.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines should NOT be taken with RIZAMELT. These include:

- Monoamine oxidase inhibitors (MAOIs) for depression such as moclobemide, phenelzine, tranylcypromine and pargyline
- Sumatriptan, a similar medicine which is also used to treat migraine.

Some medicines and RIZAMELT may interfere with each other. These include:

- Propranolol, a medicine used to treat high blood pressure
- Ergotamine, another type of medicine used to treat migraine
- Methysergide, a medicine used to treat migraine
- Sertraline, paroxetine, citalopram, escitalopram or fluoxetine, which are selective serotonin re-uptake inhibitors (SSRIs) used to treat depression
- Venlafaxine and duloxetine which are SNRIs – serotonin norepinephrine reuptake

inhibitors used to treat depression.

These medicines may be affected by RIZAMELT or may affect how well it works. You may need different amounts of your medicines or need to take different medicines. Sometimes the timing of taking the medicines is all that is needed to ensure they do not interact.

Your doctor and pharmacist have more information on medicines to be careful with or avoid whilst taking this medicine.

How to take RIZAMELT

Follow all directions given to you by your doctor or pharmacist 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 much to take

The usual dosage is one 10 mg RIZAMELT orodispersible tablet. Reduction of the headache pain to mild or none can occur within 30 minutes.

If the first orodispersible tablet **DOES** help your migraine but the migraine comes back later, you may take another tablet. Take the second tablet at least two hours after the first. Do not take more than 3 orodispersible tablets (30 mg) in any 24 hour period.

If the first orodispersible tablet **DOES NOT** help your migraine, do not take another tablet for the same migraine attack as it is unlikely to help. It is still likely though that RIZAMELT will help during your next attack.

If you are taking **propranolol**, the usual dose to treat a migraine with RIZAMELT is one 5 mg orodispersible tablet. Do not take more than 3 of the 5mg orodispersible tablets (15 mg) in any 24 hours period. You must **NOT** take the 10 mg RIZAMELT

orodispersible tablet whilst you are taking propranolol.

How to take RIZAMELT

The RIZAMELT orodispersible tablet is packaged in a blister pack within an outer aluminium sachet (pouch). Do not remove the tablet from the blister pack until just prior to dosing.

With clean, dry hands, open the outer aluminium sachet. Peel the blister pack open as indicated on the pack and place the orodispersible tablet on the tongue. It will dissolve on the tongue in the mouth and be swallowed with the saliva. It is not necessary to take RIZAMELT orodispersible tablets with liquid.

It does not matter if you take RIZAMELT with or without food.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much RIZAMELT. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include sleepiness, dizziness, feeling faint or having a slow heartbeat.

While you are using RIZAMELT

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking RIZAMELT.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

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

Things you must not do

Do not give your medicine 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 RIZAMELT affects you.

This medicine may cause dizziness, light-headedness, drowsiness, in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If you drink alcohol, sleepiness, dizziness or light-headedness may be worse when you take RIZAMELT.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking RIZAMELT.

This medicine helps most people with migraine headaches but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention 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.

Tell your doctor if you have any of the following side effects and they worry you:

Difficulty working because of:

- sleepiness, tiredness
- dizziness

- nervousness
- agitation
- inability to sleep (insomnia)
- decreased mental sharpness
- hallucinations: seeing and hearing things that are not there.

Stomach and bowel problems:

- nausea and vomiting
- stomach upset or pain
- diarrhoea.

Changes to your sight or taste:

- dry mouth
- thirst
- bad taste
- blurred vision.

Skin problems:

- hot flushes or sweating
- redness or flushing of face
- skin rash, itching.

Other side effects:

- muscle weakness
- muscle pain
- tingling or numbness of the hands or feet
- tremor, unsteadiness when walking
- spinning sensation (vertigo)
- heaviness or tightness on parts of the body
- very high temperature
- increased reflexes or lack of co-ordination
- fast or irregular heartbeats or palpitations
- neck or face pain.

Tell your doctor immediately or go to accident and emergency at your nearest hospital if you experience any of the following:

- fainting, coma
- itchy rash or swelling/hives on the skin
- swelling of the face, lips, tongue or throat
- difficulty in breathing or swallowing
- shortness of breath or wheezing
- chest pain or tightness
- collapse, numbness or weakness of the arms or legs,
- headache, dizziness and confusion
- visual disturbances
- slurred speech or loss of speech
- severe skin reaction with blisters and skin peeling, with fever and

- chills and generally feeling unwell
- seizures, fits or convulsions
 - pain or spasms in the lower stomach
 - bloody diarrhoea and fever.

A combination of these side effects may be indicative of a heart attack, angina or a stroke.

These are serious adverse effects. You may need urgent medical attention. Serious adverse effects are rare. 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.

Ask your doctor or pharmacist to answer any questions you may have.

After using RIZAMELT

Storage

Keep your tablets in the sealed packet until it is time to take them.

If you take the tablets out of the blister pack they may not keep well.

Keep your RIZAMELT tablets in a cool dry place where the temperature stays below 25°C.

Do not store RIZAMELT 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 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 this medicine or the expiry

date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

RIZAMELT 10 mg is a white to off-white coloured, round, flat faced bevelled edged tablet with "M" on one side and "RN2" on the other side.

RIZAMELT 5 mg is a white to off-white coloured, round, flat faced bevelled edged tablet with "M" on one side and "RN1" on the other side.

Ingredients

RIZAMELT 10 mg contains 10 mg of rizatriptan benzoate as the active ingredient.

RIZAMELT 5 mg contains 5 mg of rizatriptan benzoate as the active ingredient. (Not marketed in New Zealand).

They also contain:

- Colloidal anhydrous silica
- Crospovidone
- Mannitol
- Microcrystalline cellulose
- Magnesium stearate
- Aspartame
- Peppermint flavour.

RIZAMELT Orodispersible tablets are lactose and gluten free.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Eilerslie,
Auckland.
Telephone: (09) 579 2792

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13 January 2012
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