

Package leaflet: Information for the user: Zomig Rapimelt 2.5mg orodispersible tablets

zolmitriptan

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Zomig Rapimelt is and what it is used for
2. Before you take Zomig Rapimelt
3. How to take Zomig Rapimelt
4. Possible side effects
5. How to store Zomig Rapimelt
6. Further information

1 What Zomig Rapimelt is and what it is used for

Zomig Rapimelt contains zolmitriptan and belongs to a group of medicines called triptans. **Zomig Rapimelt is used to treat migraine headache.**

- Migraine symptoms may be caused by swollen blood vessels in the head. Zomig Rapimelt is thought to reduce the widening of these blood vessels. This helps to take away the headache and other symptoms of a migraine attack, such as feeling or being sick (nausea or vomiting) and being sensitive to light and sound.
- Zomig Rapimelt works only when a migraine attack has started. It will not stop you from getting an attack.

2 Before you take Zomig Rapimelt

Do not take Zomig Rapimelt if:

- You are allergic (hypersensitive) to zolmitriptan or any of the other ingredients of this medicine (see Section 6: Further information).
- You have high blood pressure.
- You have poor blood circulation, usually affecting the legs and arms (peripheral vascular disease).
- You have ever had heart problems, including a heart attack, angina (chest pain caused by exercise or effort), Prinzmetal's angina (chest pain which happens at rest) or have experienced heart related symptoms such as shortness of breath or pressure over the chest.
- You have had a stroke or short-lasting symptoms similar to stroke (transient ischaemic attack or TIA).
- You are at the same time taking some other medicines for migraine (e.g. ergotamine or ergot-type medicines like dihydroergotamine and methysergide) or other triptan medicines for migraine. See section below: 'Taking other medicines' for further information.
- You have severe kidney problems.

Do not take Zomig Rapimelt if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Zomig Rapimelt.

Take special care with Zomig Rapimelt

Before you take Zomig Rapimelt, tell your doctor if:

- You are at risk of getting ischaemic heart disease (poor blood flow in the arteries of the heart). Your risk is greater if you are a man over 40 or a woman who has reached the menopause, if you smoke, have high blood pressure, high levels of cholesterol or diabetes or if anyone in your family has ischaemic heart disease.

- You have been told that you have Wolff-Parkinson-White Syndrome (a type of abnormal heart beat).
- You have ever had liver problems.
- You have headaches which are not like your usual migraine headache.

If you go into hospital tell the medical staff you are taking Zomig Rapimelt.

Zomig Rapimelt is not recommended for people aged under 18 years or over 65.

As with other migraine treatments, using too much Zomig Rapimelt can cause daily headaches or can make your migraine headaches worse. Ask your doctor if you think that this is the case for you. You may need to stop taking Zomig Rapimelt to correct the problem.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes herbal medicines and medicines you buy without prescription. In particular, tell your doctor if you are taking any of the following medicines:

Medicines for migraine

- If you take a triptan other than Zomig Rapimelt (such as sumatriptan or naratriptan) leave 12 hours before taking Zomig Rapimelt.
- After taking Zomig Rapimelt leave 12 hours before taking another triptan.
- If you take medicines containing ergotamine or ergot-type medicines (such as dihydroergotamine or methysergide), leave 24 hours before taking Zomig Rapimelt.
- After taking Zomig Rapimelt leave 6 hours before taking ergotamine or ergot-type medicines.

Medicines for depression

- Mono-Amine Oxidase Inhibitors, also known as MAOIs (such as moclobemide).
- SSRIs (selective serotonin reuptake inhibitors) such as fluoxetine, paroxetine, fluvoxamine or sertraline.
- SNRIs (serotonin norepinephrine reuptake inhibitors) such as venlafaxine or duloxetine.

Other medicines

- Cimetidine (for indigestion or stomach ulcers).
- A quinolone antibiotic (such as ciprofloxacin).

You should not take the herbal remedy St. John's wort (*Hypericum perforatum*) at the same time as this medicine. If you already take a St. John's wort preparation, stop taking it and mention this to your doctor at your next visit.

Taking Zomig Rapimelt with food and drink

You can take Zomig Rapimelt with or without food. It does not affect the way that Zomig Rapimelt works.

Pregnancy and breast-feeding

- It is not known if taking Zomig Rapimelt during pregnancy is harmful. Before taking Zomig Rapimelt, tell your doctor if you are pregnant or trying to become pregnant.
- Before taking Zomig Rapimelt tell your doctor if you are breast-feeding.

Driving and using machines

- During a migraine attack your reactions may be slower than usual. Bear this in mind when you drive or use any tools or machines.
- Zomig Rapimelt is unlikely to affect driving or using tools or machines. However, it may make you feel sleepy. Wait to see how Zomig Rapimelt affects you before you try these activities.

Important information about some of the ingredients of Zomig Rapimelt

Zomig Rapimelt 2.5 mg orodispersible tablets contain aspartame, a source of phenylalanine, which may be harmful for people with phenylketonuria.

3 How to take Zomig Rapimelt

Always take Zomig Rapimelt exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

You can take Zomig Rapimelt as soon as a migraine headache starts. You can also take it once an attack is underway.

- The usual dose is one tablet (2.5 mg).
- Peel the blister pack open as shown on the foil. Do not push the tablet through the foil.
- Place the tablet on your tongue, where it will dissolve and be swallowed with the saliva. You do not have to take a drink of water in order to swallow your tablet.
- You can take another tablet if the migraine is still present after two hours or if it returns within 24 hours.

If the tablets did not give you enough help with your migraine, tell your doctor. Your doctor may change your treatment.

Do not use more than the dose prescribed for you.

- Do not use more than two doses of one tablet (two doses of 2.5 mg) in a day unless prescribed to by your doctor.
- The maximum daily dose is 10 mg.

If you take more Zomig Rapimelt than you should

If you have taken more Zomig Rapimelt than prescribed by your doctor, tell your doctor or go to the nearest hospital straight away. Take the Zomig Rapimelt medicine with you.

4 Possible side effects

Like all medicines, Zomig Rapimelt can cause side effects, although not everybody gets them. Some of the symptoms below could be part of the migraine attack itself.

Stop taking Zomig Rapimelt and contact your doctor straight away if you notice any of the following:

Rare (affects less than 1 in 1,000 people)

- Allergic reactions including itchy rash (urticaria) and swelling of the face, lips, mouth, tongue and throat.

Very rare (affects less than 1 in 10,000 people)

- Angina (pain in the chest, often brought on by exercise), heart attack or spasm of the blood vessels of the heart. The signs include chest pain and shortness of breath.
- Spasm of the blood vessels of the gut, which can cause damage to your gut. The signs include stomach pain or bloody diarrhoea.

Other possible side effects:

Common (affects less than 1 in 10 people):

These side effects are usually mild and go away after a short time.

- Abnormal sensations such as tingling in your fingers and toes or skin that is sensitive to touch.
- Feeling sleepy, dizzy or warm.
- Headache.
- Uneven heart beat.
- Feeling sick (nausea) or being sick (vomiting).
- Stomach pain.
- Dry mouth.
- Muscle weakness or muscle pain.
- Feeling weak.
- Heaviness, tightness, pain or pressure in the throat, neck, arms and legs, or chest.

Uncommon (affects less than 1 in 100 people):

- Very fast heart beat.
- Slightly higher blood pressure.

- Increase in the amount of water you pass (urine) or in how often you need to pass water.

Do not be concerned by this list of possible side effects. You may not get any of them. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 How to store Zomig Rapimelt

- Keep out of the reach and sight of children.
- Keep your medicine in the container it came in.
- Do not use Zomig Rapimelt after the expiry date (EXP) stated on the carton and blister. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further Information

What Zomig Rapimelt 2.5 mg orodispersible tablets contain

The active ingredient is zolmitriptan. Zomig Rapimelt 2.5 mg orodispersible tablets contain 2.5 mg of zolmitriptan. The other ingredients are: aspartame (E951), citric acid anhydrous, silica colloidal anhydrous, crospovidone, magnesium stearate, mannitol, microcrystalline cellulose, orange flavour (SN027512) and sodium hydrogen carbonate.

What Zomig Rapimelt 2.5 mg orodispersible tablets look like and contents of the pack

- Zomig Rapimelt 2.5 mg orodispersible tablets are white, flat-faced, round and marked with the letter 'Z' on one side.
- Zomig Rapimelt 2.5 mg orodispersible tablets come in peelable aluminium laminate blister packs containing 6 tablets.

Product procured from within the EU by the Parallel Product Authorisation Holder:

IMED Healthcare Ltd, New Road, Buncrana, Co. Donegal, Ireland.

Manufacturer

AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, UK

Repackaged by

IMED Pharma Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15

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- You are at the same time taking some other medicines for migraine (e.g. ergotamine or ergot-type medicines like dihydroergotamine and methysergide) or other triptan medicines for migraine. See section below: 'Taking other medicines' for further information.
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