Package leaflet: Information for the user

Zomig Rapimelt 2.5 mg orodispersible tablets
zolmitriptan

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet:

1. What Zomig Rapimelt is and what it is used for
2. What you need to know before you take Zomig Rapimelt
3. How to take Zomig Rapimelt
4. Possible side effects
5. How to store Zomig Rapimelt
6. Contents of the pack and other 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. What you need to know before you take Zomig Rapimelt

Do not take Zomig Rapimelt:
- If you are allergic to zolmitriptan or any of the other ingredients of this medicine (listed in Section 6).
- If you have high blood pressure.
- If 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.
- If you have had a stroke or short-lasting symptoms similar to stroke (transient ischaemic attack or TIA).
- If 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 '**Other medicines and Zomig Rapimelt**' for further information.

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.

Warnings and precautions
Talk to your doctor of pharmacist before taking Zomig Rapimelt:
- 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 smoke, have high blood pressure, high levels of cholesterol, diabetes or if anyone in your family has ischaemic heart disease.
- If you have been told that you have Wolff-Parkinson-White Syndrome (a type of abnormal heart beat).
- If you have ever had liver problems.
- If you have headaches which are not like your usual migraine headache.
- If you are taking any medicine for treatment of depression (see '**Other medicines and Zomig Rapimelt**' for further information).

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

Zomig Rapimelt is not recommended for people aged 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.

Children and adolescents
Zomig Rapimelt is not recommended in children and adolescents under 18 years.

Other medicines and Zomig Rapimelt
Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 24 hours before taking Zomig Rapimelt.
- After taking Zomig Rapimelt leave 24 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. Serotonin syndrome is a rare, life-threatening condition that has been reported in some patients who took Zomig in combination with so called serotoninergic medicines (e.g. certain medicines for the treatment of depression). Signs of serotonin syndrome may be for example agitation, restlessness, fever, excessive sweating, tremor, uncoordinated movement of limbs or eyes, uncontrollable jerking of muscles, twitching and muscle rigidity. Your doctor may advise you on this.

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.

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, breast-feeding and fertility
It is not known if taking Zomig Rapimelt during pregnancy is harmful. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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.

Zomig Rapimelt contains Aspartame (E951)
Zomig Rapimelt 2.5 mg orodispersible tablets contains 5 mg aspartame per tablet. Aspartame is a source of phenylalanine.
It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Zomig Rapimelt contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Zomig Rapimelt contains benzyl alcohol
Zomig Rapimelt 2.5 mg contains 0.0000032 mg of benzyl alcohol in each orodispersible tablet. Benzyl alcohol may cause allergic reactions.
Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build up in your body and may cause side effects (called "metabolic acidosis").
Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build up in your body and may cause side effects (called "metabolic acidosis").

3. How to take Zomig Rapimelt

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

- The recommended 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 in one day unless prescribed 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, talk to your doctor or pharmacist straight away or go to the nearest hospital straight away. Take this medicine with you.

If you forget to take Zomig Rapimelt
- Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

If you notice any of the following serious side effects, stop taking Zomig Rapimelt and contact a doctor straight away:

Rare (may affect up to 1 in 1,000 people):
- Allergic reactions including itchy rash (urticaria) and swelling of the face, lips, mouth, tongue and throat.

Very rare (may affect up to 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.
- Bleeding in the brain (cerebral bleeding) or stroke.

Other possible side effects include:

Common (may affect up to 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.
- Problems swallowing.

Uncommon (may affect up to 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.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zomig Rapimelt

- Keep this medicine out of the sight and reach of children.
- Keep your medicine in the container it came in.
- Do not use this medicine after the expiry date stated on the carton. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Zomig Rapimelt 2.5 mg orodispersible tablet contains
The active substance is zolmitriptan. Each tablet contains 2.5 mg of zolmitriptan.

The other ingredients are: aspartame (E951), citric acid anhydrous, silica colloidal anhydrous, crospovidone, magnesium stearate, mannitol (E421), microcrystalline cellulose, orange flavour (contains benzyl alcohol) 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.

Zomig may also be available as orodispersible 5 mg tablets, nasal spray 5 mg/dose and film-coated tablets 2.5 mg.

Marketing Authorisation Holder and Manufacturer
The Marketing Authorisation for Zomig Rapimelt 2.5 mg orodispersible tablets is held by Grünenthal Ltd, TOR Building, Saint Cloud Way, Maidenhead, Berkshire, SL6 8BN, United Kingdom.

Zomig Rapimelt 2.5 mg orodispersible tablets are manufactured by Farmaceutici Formenti S.p.A. Via Di Vittorio 2, 21040 Origgio (VA) Italy *or* Grünenthal GmbH, Zieglerstraße 6, 52078 Aachen, Germany.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)
Please be ready to give the following information:

Product name **Zomig Rapimelt 2.5 mg**
Reference number PL 21727/0083

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in:

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