

Package leaflet: Information for the user

Zomig® 2.5 mg 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 is and what it is used for
2. What you need to know before you take Zomig
3. How to take Zomig
4. Possible side effects
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1. What Zomig is and what it is used for

Zomig contains zolmitriptan and belongs to a group of medicines called triptans.

Zomig is used to treat migraine headache.

- Migraine symptoms may be caused by swollen blood vessels in the head. Zomig 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 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

Do not take Zomig:

- If you are allergic (hypersensitive) to zolmitriptan or any of the other ingredients of this medicine (listed in Section 6).
- If you have high blood pressure.
- If you have poor blood circulation, usually affecting the legs and arms (peripheral vascular disease).
- 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 section below: 'Taking other medicines' for further information.
- If you have severe kidney problems.

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Zomig:

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

Zomig is not recommended for people over 65 years.

Children and adolescents

Zomig is not recommended for people aged under 18 years.

As with other migraine treatments, using too much Zomig 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 to correct the problem.

Other medicines and Zomig

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 (such as sumatriptan or naratriptan) leave 24 hours before taking Zomig.
- After taking Zomig 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.
- After taking Zomig 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 serotonergic medicines (e.g. certain medicines for the treatment of depression). Signs of serotonin syndrome may be for example, agitation, tremor, restlessness, fever, excessive sweating, twitching, muscle rigidity uncoordinated movement of limbs or eyes and uncontrollable jerking of muscles. 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 with food and drink

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

Pregnancy, breast-feeding and fertility

It is not known if taking Zomig 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 is unlikely to affect driving or using tools or machines. However, it may make you feel sleepy. Wait to see how Zomig affects you before you try these activities.

Zomig contains Lactose

Zomig 2.5 mg tablets contain lactose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicine.

Zomig contains sodium:

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

3. How to take Zomig

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).
- Swallow your tablet with a drink of water.
- 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 than you should

If you take more Zomig than prescribed by your doctor, talk to your doctor or pharmacist straight away or go to the nearest hospital straight away. Take the Zomig medicine with you.

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

If you forget to take Zomig

- 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 side effects, stop taking Zomig 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.

Other 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.
- Difficulty in 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.

Very rare (may affect up to 1 in 10,000 people)

- Sudden urgent need to pass water (urine).

Do not be concerned by this list of possible side effects. You may not get any of them.

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 HPRC Pharmacovigilance.

Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zomig

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.
- Store this medicine in the original package.
- 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 contains**

The active substance is zolmitriptan. Each tablet contains 2.5 mg of zolmitriptan.

The other ingredients are: Lactose anhydrous, microcrystalline cellulose, sodium carboxymethyl starch, magnesium stearate, macrogol 8000, OPARDY yellow OY-22906.

What Zomig looks like and contents of the pack

- Zomig 2.5 mg tablets are yellow, round and marked with the letter 'Z' on one side.
- Your tablets will come in blister packs containing 6 tablets.

Parallel Product Authorisation Holder

IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland.

Manufacturer

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