

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some of the common questions people ask about Zomig. It does not contain all the information that is known about Zomig.

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 Zomig 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 Zomig is for

Zomig belongs to a group of medicines called serotonin agonists. These medicines are used to relieve migraine.

Migraine is thought to be caused by the widening of certain blood vessels in the brain. Zomig makes the blood vessels narrower to ease the migraine.

Some people have a warning stage called 'aura' before the migraine headache starts. Aura can include numbness in the face or down one arm, changes in mood, or problems with eyesight such as seeing blank spots or flashing lights.

Zomig can be used in migraine with or without aura. It should not be used to treat types of migraine

called 'hemiplegic' or 'basilar' migraine.

Zomig does not work in headaches that are not migraine.

Your doctor will have explained why you are being treated with Zomig and told you what dose to take.

**Follow all directions given to you by your doctor carefully.**

They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

Zomig is not addictive.

### Before you take Zomig

*When you must not take it*

**Do not use Zomig if you are pregnant or breastfeeding unless your doctor says so.**

We do not know if it is safe for you to take it while you are pregnant.

**Do not give Zomig to children.**

There is no experience of its use in children under 12 years of age. One study in children aged 12 to 17 years indicated no benefit with Zomig treatment.

**Do not use Zomig after the use by (expiry) date printed on the pack.**

It may have no effect at all, or an unexpected effect, if you take it after the expiry date.

**Do not use Zomig if the packaging is torn or shows signs of tampering.**

**Do not give this medicine to anyone else.**

*Before you start to use it*

**You must tell your doctor if:**

**1. you have any allergies to**

- any ingredient listed at the end of this leaflet
  - any other substances
- If you have an allergic reaction, you may get a skin rash, hayfever, difficulty breathing or feel faint.

**2. you have or have had any of these medical conditions**

- high blood pressure
- a feeling of tightness, pressure or heaviness in the chest
- a heart attack, other heart problems or a family history of heart problems
- a stroke or dizzy spells caused by lack of blood flow to the brain
- blood vessel problems that cause poor circulation in the arms or legs
- kidney or liver disease
- high cholesterol levels in the blood
- diabetes

It may not be safe for you to take Zomig if you have any of these conditions. Your doctor may decide to do tests to check if your heart is healthy before prescribing Zomig tablets.

*Taking other medicines*

**Tell your doctor if you are taking any other medicines, including:**

- other medicines for migraine, such as sumatriptan, naratriptan, ergotamine, dihydroergotamine or methysergide

- medicines for depression (see also Side effects section)
- cimetidine for the treatment of indigestion or stomach ulcers
- antibiotics known as quinolones (eg noroxin).
- St John's Wort (*Hypericum perforatum*)
- any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

These medicines may affect the way Zomig works. Your doctor or pharmacist can tell you what to do if you are taking any other medicines.

**If you have not told your doctor about any of these things, tell them before you take any Zomig.**

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## Taking Zomig

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

### *How much to take*

The usual dose is one tablet (2.5 mg) as soon as you feel the migraine headache start.

**If your migraine is still present after two hours, or if it returns within 24 hours, you can take another tablet.**

**Do not take more than 10 mg (four 2.5 mg tablets) in twenty-four hours.**

**Swallow your Zomig tablets whole with a glass of water.**

You can take them before or after food.

### *When to take it*

**You can take Zomig when you feel the headache start or after it has already begun.**

Zomig tablets should only be taken to treat the migraine headache after

it has started. They should not be used to prevent the migraine attacks from occurring.

### *Overdose*

**Immediately telephone your doctor or the Poisons Information Centre (13 11 26), or go to casualty at your nearest hospital if you think that you or anyone else may have taken too much Zomig even if there are no signs of discomfort or poisoning.**

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## While you are taking Zomig

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### *Things you must do*

**If you go into hospital tell the staff if you have taken any Zomig that day.**

If you are about to start taking any other medicine, tell your doctor and pharmacist that you are taking Zomig.

### *Things you must not do*

**Do not give Zomig to anyone else, even if they have the same condition as you.**

**Do not use Zomig tablets to treat any other complaints unless your doctor tells you to.**

### *Things to be careful of*

**Be careful driving or operating machinery until you know how Zomig affects you.**

Zomig can make some people feel dizzy or sleepy. Make sure you know how you react to Zomig before you do anything that could be dangerous if you are dizzy or sleepy.

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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 Zomig.**

Zomig helps most people with migraine, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side 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:**

- increased feeling or sensitivity, especially in the skin
- feeling warm
- feelings of heaviness, tightness, pain or pressure in the throat, neck, arms or legs
- unusual tiredness or weakness
- aching muscles not caused by exercise
- dizziness
- nausea
- stomach pain
- vomiting
- headache
- palpitations (irregular heart beat)
- sleepiness
- dry mouth

These are all common and mild side effects of Zomig.

**If any of the following happen, stop taking Zomig and tell your doctor immediately or go to the emergency department at your nearest hospital.**

- wheezing, difficulty in breathing, swelling of the lips or mouth, a lumpy rash (hives) or fainting.
- a feeling of tightness, pressure or heaviness in the chest
- irregular heartbeats/ increased heart rate
- numbness or loss of strength of the arms or legs, headache, dizziness, confusion, visual disturbance, difficulty

- swallowing, slurred speech or loss of speech
- confusion, restlessness, fever, sweating, uncoordinated movement of limbs or eyes, uncontrollable jerking of muscles, myoclonus and/or diarrhoea. – particularly in patients who are also taking medicines to treat depression (Serotonin syndrome)
- bloody diarrhoea or prolonged stomach pain

These are serious side effects. If you have them, you may have had a serious reaction to Zomig. You may need urgent medical attention or hospitalisation. Serious side effects are rare.

**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 using Zomig to correct the problem.**

Some people may get other side effects while taking Zomig

**Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.**

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## After using Zomig

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### *Storage*

**Keep your tablets in the blister pack until it is time to take them.**

If you take Zomig out of the blister pack it will not keep well.

**Keep it in a cool dry place where the temperature stays below 25 degrees Celsius.**

**Do not store it or any other medicine in the bathroom or near a sink.**

Heat and dampness can destroy some medicines.

**Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

**Do not leave it in the car on hot days.**

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## Disposal

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**Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.**

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## Product description

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### *What Zomig looks like*

Zomig 2.5 mg is a round, yellow-coloured tablet with a Z on one side. Zomig 2.5 mg tablets are presented in a blister pack containing 2 tablets.

### *Ingredients*

Each Zomig tablet contains

2.5 mg zolmitriptan as the active ingredient; plus,

- hypromellose
- lactose
- magnesium stearate (E 572)
- microcrystalline cellulose (E 460)
- sodium starch glycolate
- titanium dioxide (E 171)
- iron oxide yellow CI77492 (E 172)
- macrogols

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## Manufacturer

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Web: [www.aspenpharma.com.au](http://www.aspenpharma.com.au)

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Zomig 2.5 mg tablets: AUST R 61325

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