

Package leaflet: Information for the patient

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

1. What Zolmitriptan is and what it is used for

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

Zolmitriptan is used to treat migraine headache.

Migraine symptoms may be caused by the widening of blood vessels in the head. Zolmitriptan 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.

Zolmitriptan 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 Zolmitriptan

Do not take Zolmitriptan

- 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 poor blood circulation, usually affecting the legs and arms (peripheral vascular disease)
- if you have had a stroke or short-lasting symptoms similar to stroke (transient ischaemic attack or TIA)
- if you have severe kidney problems
- 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: 'Other medicines and Zolmitriptan' for further information.

Do not take Zolmitriptan if any of the above apply to you. If you are not sure if any of these apply to you, talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zolmitriptan 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, 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 as your dose of Zolmitriptan may need to be adjusted
- you have headaches which are not like your usual migraine headache
- you are taking any other medicine for treatment of depression (see 'Other medicines and Zolmitriptan' later in this section).

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

If you are treated with both Zolmitriptan and certain types of antidepressants, then your doctor will need to carefully monitor you.

If you use any type of painkiller while taking Zolmitriptan, then your headaches could get worse. If this happens, speak to your doctor as soon as possible.

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

Children and adolescents

Zolmitriptan is not recommended for people aged under 18 years

Elderly

Zolmitriptan is not recommended for people over 65.

Other medicines and Zolmitriptan

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 a prescription. In particular, tell your doctor if you are taking any of the following medicines:

Medicines for migraine

- if you take other triptans than zolmitriptan (such as sumatriptan or naratriptan) leave 24 hours before taking Zolmitriptan, and after taking Zolmitriptan leave 24 hours before taking any other triptans.
- if you take medicines containing ergotamine or ergot-type medicines (such as dihydroergotamine or methysergide), leave 24 hours before taking Zolmitriptan, and after taking Zolmitriptan leave 6 hours before taking ergotamine or ergot-type medicines.

Medicines for depression (see also section 'Warnings and precautions' above)

- Mono-Amino Oxidase Inhibitors, also known as MAOIs such as moclobemide
- medicines called SSRIs (selective serotonin reuptake inhibitors), such as fluoxetine, paroxetine, fluvoxamine or sertraline
- medicines called 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 Zolmitriptan 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 on your next visit.

Zolmitriptan with food and drink

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

Pregnancy, breast-feeding and fertility

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.

It is not known if taking Zolmitriptan during pregnancy is harmful.

Do not breast-feed within 24 hours of taking Zolmitriptan.

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.

Zolmitriptan is unlikely to affect driving or using tools or machines. However, it may make you sleepy. Wait to see how Zolmitriptan affects you before you try these activities.

Zolmitriptan contains aspartame

Zolmitriptan orodispersible tablets contain aspartame, a source of phenylalanine. May be harmful for people with phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Zolmitriptan contains sodium

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

3. How to take Zolmitriptan

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

The recommended dose is one 2.5mg tablet (2.5 mg zolmitriptan) or two 2.5 mg tablets (5 mg zolmitriptan).

You can take another 2.5 mg tablet (2.5 mg zolmitriptan) or two 2.5 mg tablets (5 mg zolmitriptan) 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 raise the dose to 5 mg or change your treatment.

Do not use more than the dose prescribed for you.

Do not use more than two doses in one day. If you have been prescribed one 2.5 mg tablet (2.5 mg zolmitriptan), the maximum daily dose is two 2.5 mg tablets (5 mg zolmitriptan). If you have been prescribed two 2.5 mg tablets (5 mg zolmitriptan), the maximum daily dose is four 2.5 mg tablets (10 mg zolmitriptan).

Instruction for use

Push the tablet out of the blister pocket with dry hands and place it on the tongue (Figure 1). It will rapidly disintegrate and can be swallowed without water.

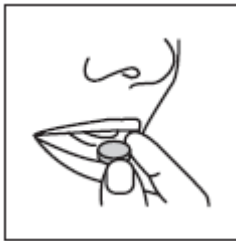


Figure 1

If you take more Zolmitriptan than you should

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

When too many orodispersible tablets are taken the symptoms may possibly include sedation.

If you forget to take Zolmitriptan

Do not use more than the dose prescribed for you.

- Do not take a double dose to make up for a forgotten dose or use more than four doses of one tablet (four doses of 2.5mg) in a day unless prescribed by your doctor.
- The maximum daily dose is 10mg

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 Zolmitriptan 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 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
- Difficulty swallowing
- Muscle weakness or muscle pain
- Feeling weak
- Heaviness, tightness, pain or pressure in throat, neck, arms and legs, or chest

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 about this list of possible side effects. You may not get 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 HPRA 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 Zolmitriptan

Keep out of the sight and reach of children.

Do not use Zolmitriptan after the expiry date which is stated on the blister and the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30°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 Zolmitriptan contains

- The active substance is zolmitriptan. Zolmitriptan orodispersible tablets contain 2.5 mg of zolmitriptan.
- The other ingredients are mannitol (E421), calcium silicate, microcrystalline cellulose, aspartame (E951), sodium starch glycolate type A, crospovidone type B, colloidal anhydrous silica, magnesium stearate and orange cream flavour (containing e.g. maltodextrin (maize), acacia (E414), ascorbic acid (E300), butylhydroxyanisole (E320)).

What Zolmitriptan looks like and contents of the pack

Zolmitriptan 2.5 mg orodispersible tablets are white, round, flat faced, bevel edges uncoated tablets debossed with “Z1” on one side and plain on other side.

Zolmitriptan orodispersible tablets 2.5 mg come in peelable aluminium laminate or Alu/Alu blister packs containing 2, 3, 6 or 12 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer

Actavis Ltd
BLB016, Bulebel Industrial Estate
Zejtun ZTN3000
Malta

Or

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