

Zolmitriptan 2.5mg and 5mg Orodispersible Tablets

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.

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1 What Zolmitriptan tablets are and what they are used for

Zolmitriptan tablets contain 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 tablets

Do not take Zolmitriptan tablets if you

- are **allergic** to zolmitriptan or any of the other ingredients of this medicine (listed in section 6)
- have **high blood pressure**
- 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
- have had a **stroke** or short-lasting symptoms similar to stroke (transient ischaemic attack or TIA)
- 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 tablets' for further information.

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 tablets 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
- have been told that you have Wolff-Parkinson-White Syndrome (a type of abnormal heartbeat)
- have ever had liver problems
- have headaches which are not like your usual migraine headache
- are taking any medicine for treatment of depression (see 'Other medicines and Zolmitriptan tablets' later in this section).

As with other migraine treatments, taking 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 taking zolmitriptan to correct the problem.

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

Older people

Zolmitriptan is not recommended for people over 65.

Other medicines and Zolmitriptan tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor if you are taking any of the following medicines:

Medicines for migraine

- if you take a triptan other 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 after taking Zolmitriptan leave 6 hours before taking ergotamine or ergot-type medicines.

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

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

If you are using herbal remedies containing St John's Wort (*Hypericum perforatum*), side effects of Zolmitriptan may be more likely to happen.

Zolmitriptan tablets with food and drink

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

Pregnancy and breast-feeding

It is not known if taking Zolmitriptan 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.

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

This medicine contains aspartame.

Zolmitriptan 2.5mg orodispersible tablets contain 4.00mg aspartame per tablet. Zolmitriptan 5mg orodispersible tablets contain 8.00mg 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.

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

3 How to take Zolmitriptan tablets

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 tablet (either 2.5mg or 5mg). You can take another tablet if the migraine is still present after two hours **or** if it returns within 24 hours.

If the 2.5mg tablets did not give you enough help with your migraine, tell your doctor. Your doctor may raise the dose to 5mg or change your treatment.

Do not take more than the dose prescribed for you.

Do not take more than two doses in one day. If you have been prescribed the 2.5mg tablet, the maximum daily dose is 5mg. If you have been prescribed the 5mg tablet, the maximum daily dose is 10mg.

Instruction for use

1. Do not push the tablet out of the pocket (Figure 1).



Figure 1

2. Separate one blister cell from the strip (Figure 2).



Figure 2

3. Carefully peel off the lidding foil starting at the corner as indicated by the arrow (Figures 3 and 4).



Figure 3



Figure 4

4. Take the tablet out of the pocket with dry hands and place it on the tongue (Figure 5). It will rapidly disintegrate and can be swallowed without water.



Figure 5

If you take more Zolmitriptan than you should

If you have taken more Zolmitriptan than prescribed by your doctor, talk to your doctor or pharmacist or go to the nearest hospital straight away. Take this medicine with you. When too many orodispersible tablets are taken, symptoms may include sedation.

If you forget to take Zolmitriptan tablets

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 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
- Bleeding in the brain (cerebral bleeding) or stroke.

Other possible side effects include:

Common (may affect up to 1 in 10 people):

- Abnormal sensations such as tingling in your fingers and toes or skin that is sensitive to touch
- Feeling sleepy, dizzy or warm
- Headache
- Uneven heartbeat
- Feeling 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 heartbeat
- Slightly higher blood pressure
- Increase in the amount of water you pass (urine) or 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).

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, Website: 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 Zolmitriptan tablets

Keep out of the sight and reach of children.

Do not take 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 tablets contain

- The active substance is zolmitriptan. Zolmitriptan orodispersible tablets contain either 2.5mg or 5mg 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 tablets look like and contents of the pack

Zolmitriptan 2.5mg orodispersible tablets are white and round flat tablets with the diameter 7.5mm. Zolmitriptan 5mg orodispersible tablets are white and round flat tablets with the diameter 9.5mm.

Zolmitriptan orodispersible tablets 2.5mg and 5mg come in peelable aluminium laminate blister packs containing 6 or 12 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Accord, Barnstaple, EX32 8NS, UK

Manufacturer

Actavis Ltd
BLB016, Bulebel Industrial Estate
Zejtun ZTN3000
Malta

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