

Zolmitriptan 2.5mg Film-coated 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.

What is in this leaflet:

- 1 What Zolmitriptan tablets are and what they are used for
- 2 What you need to know before you take Zolmitriptan tablets
- 3 How to take Zolmitriptan tablets
- 4 Possible side effects
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1 What Zolmitriptan tablets are and what they are used for

Zolmitriptan tablets contain zolmitriptan and belong 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, 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 taking zolmitriptan to correct the problem.

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

Zolmitriptan is not recommended for people over 65.

Children and adolescents

Zolmitriptan is not recommended in children and adolescents under 18 years.

Other medicines and Zolmitriptan tablets

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 zolmitriptan (such as sumatriptan or naratriptan) leave 24 hours before taking Zolmitriptan.
- 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

- 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.

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.

Zolmitriptan tablets with food and drink

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

Zolmitriptan tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

- The recommended dose is one 2.5 mg tablet.
- Swallow your tablet with a drink of water.
- You can take another 2.5 mg 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 take more than the dose prescribed for you.

- Do not take more than two doses in one day unless prescribed to by your doctor
- The maximum daily dose is 10 mg.

If you take more Zolmitriptan tablets than you should

If you take more Zolmitriptan 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 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 tablets 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 heartbeat
- 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 heartbeat
- 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).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Zolmitriptan tablets

Keep this medicine out of the sight and reach of children.

Do not take this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 film-coated tablets contain 2.5mg of zolmitriptan.
- The other ingredients are: tablet core: lactose, microcrystalline cellulose, sodium starch glycolate (Type A), magnesium stearate; tablet coating: hypromellose (E464), titanium dioxide (E171), polydextrose, talc, maltodextrin, medium chain triglycerides, iron oxide yellow (E172) and iron oxide black (E172).

What Zolmitriptan tablets look like and contents of the pack

Zolmitriptan 2.5 mg film-coated tablets are light yellow, round, biconvex tablets with 'ZL 2.5' debossed on one side.

Zolmitriptan 2.5 mg comes in blister packs containing 6 or 12 film-coated tablets.

Marketing Authorisation Holder

Accord, Barnstaple, EX32 8NS, UK

Manufacturer

Actavis Ltd.
BLB016 Bulebel Industrial Estate
Zejtun ZTN3000
Malta

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