

PACKAGE LEAFLET: INFORMATION FOR THE USER
Zolmitriptan 2.5 mg Orodispersible Tablets
Zolmitriptan 5 mg Orodispersible Tablets

Zolmitriptan

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Zolmitriptan Orodispersible Tablets are and what they are used for
2. Before you take Zolmitriptan Orodispersible Tablets
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1. WHAT ZOLMITRIPTAN ORODISPERSIBLE TABLETS ARE AND WHAT THEY ARE USED FOR

Zolmitriptan Orodispersible Tablets contain zolmitriptan and belong to a group of medicines called triptans.

Zolmitriptan Orodispersible Tablets are used to treat migraine headache.

- Migraine symptoms may be caused by the widening of blood vessels in the head. Zolmitriptan Orodispersible Tablets are 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 Orodispersible Tablets work only when a migraine attack has started. They will not stop you from getting an attack.

2. BEFORE YOU TAKE ZOLMITRIPTAN ORODISPERSIBLE TABLETS

Do not take Zolmitriptan Orodispersible Tablets if:

- you are allergic (hypersensitive) to zolmitriptan or any of the other ingredients of this medicine (see Section 6: Further information).
- you have high blood pressure.
- 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.
- you have had a stroke or short-lasting symptoms similar to stroke (transient ischaemic attack or TIA).
- you have severe kidney problems.
- 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 are not sure if any of these apply to you, talk to your doctor or pharmacist.

Take special care with Zolmitriptan Orodispersible Tablets

Before you take Zolmitriptan Orodispersible Tablets, tell your doctor 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.
- you have been told that you have Wolff-Parkinson-White Syndrome (a type of abnormal heart beat).
- you have ever had liver problems.
- you have headaches which are not like your usual migraine headache.
- you are taking any medicine for treatment of depression (see 'Taking other medicines' later in this section).

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

Zolmitriptan Orodispersible Tablets are not recommended for people aged under 18 years or over 65.

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

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken 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 triptans other than Zolmitriptan Orodispersible Tablets leave 24 hours before taking Zolmitriptan Orodispersible Tablets.
- After taking Zolmitriptan Orodispersible Tablets leave 24 hours before taking triptans other than Zolmitriptan Orodispersible Tablets.
- If you take medicines containing ergotamine or ergot-type medicines (such as dihydroergotamine or methysergide), leave 24 hours before taking Zolmitriptan Orodispersible Tablets.
- After taking Zolmitriptan Orodispersible Tablets leave 6 hours before taking ergotamine or ergot-type medicines.

Medicines for depression

- Moclobemide or fluvoxamine.
- Medicines called SSRIs (selective serotonin reuptake inhibitors)
- Medicines called SNRIs (serotonin norepinephrine reuptake inhibitors) such as venlafaxine or duloxetine.

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 Orodispersible Tablets may be more likely to happen.

Using Zolmitriptan Orodispersible Tablets with food and drink

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

Pregnancy and breast-feeding

- It is not known if taking Zolmitriptan Orodispersible Tablets during pregnancy is harmful. Before taking Zolmitriptan Orodispersible Tablets, tell your doctor if you are pregnant or trying to become **pregnant**.

You should not breastfeed 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 Orodispersible Tablets are unlikely to affect driving or using tools or machines. However, it is best to wait to see how Zolmitriptan Orodispersible Tablets affect you before you try these activities.

3. HOW TO TAKE ZOLMITRIPTAN ORODISPERSIBLE TABLETS

Always take Zolmitriptan Orodispersible Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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

- The usual dose is one tablet (either 2.5 mg or 5 mg).
- Peel the blister pack open as shown on the foil. Do not push the tablet through the foil.
- Place the tablet on your tongue, where it will dissolve and be swallowed with the saliva. You do not have to take drink of water in order to swallow your tablet.
- 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 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 the 2.5 mg tablet, the maximum daily dose is 5 mg. If you have been prescribed the 5 mg tablet, the maximum daily dose is 10 mg.

If you take more Zolmitriptan Orodispersible Tablets than you should

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Zolmitriptan Orodispersible Tablets can cause side effects, although not everybody gets them. Some of the symptoms below could be part of the migraine attack itself.

Common side effects (that affect more than 1 person in 100):

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| <ul style="list-style-type: none"> • 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. Vomiting. | <ul style="list-style-type: none"> • 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. |
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Uncommon side effects (that affect less than 1 person in 100):

- 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.

Rare side effects (that affect less than 1 person in 1000)

- Allergic reactions including itchy rash (urticaria) and swelling of the face, lips, mouth, tongue and throat.

Very rare side effects (that affect less than 1 person in 10000)

- Angina (pain in the chest, often brought on by exercise), heart attack or spasm of the blood vessels of the heart. If you notice chest pain or shortness of the breath after taking Zolmitriptan Orodispersible Tablets contact your doctor and do not take any more Zolmitriptan Orodispersible Tablets.
- Spasm of the blood vessels of the gut, which can cause damage to your gut. You may notice stomach pain or bloody diarrhoea. If this happens, contact your doctor and do not take any more Zolmitriptan Orodispersible Tablets.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ZOLMITRIPTAN ORODISPERSIBLE TABLETS

Keep out of the reach and sight of children.

Do not store above 30°C.

Do not use Zolmitriptan Orodispersible Tablets after the expiry date stated on the carton and on the blister foil. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Zolmitriptan Orodispersible Tablets contain

The active ingredient is zolmitriptan.

Zolmitriptan 2.5 mg Orodispersible Tablets contain 2.5 mg of zolmitriptan.

Zolmitriptan 5 mg Orodispersible Tablets contain 5 mg of zolmitriptan.

The other ingredients are:

Dextrates Hydrated, Silicified Microcrystalline Cellulose, Croscarmellose sodium, Sucralose, Orange Flavor (Consisting of Maize maltodextrin, flavouring preparations, flavouring substances, E 307 Alpha-tocopherol, natural flavouring substances), Magnesium Stearate.

What Zolmitriptan Orodispersible Tablets look like and content of the pack

Zolmitriptan 2.5 mg are white, round, flat tablets with a diameter of 6.5 mm approximately.

Zolmitriptan 5 mg are white, round, flat tablets with a diameter of 8.0 mm approximately.

Zolmitriptan Orodispersible Tablets are available in peelable aluminium laminate blister packs.

Pack sizes: 2, 3, 6 and 12 tablets.

Not all pack sizes may be marketed.

Zolmitriptan may also be available in film-coated tablets of 2.5 mg.



Marketing Authorisation Holder

Arrow Generics Limited, Unit 2, Eastman Way, Stevenage, Hertfordshire, SG1 4SZ, United Kingdom

Manufacturer

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