

Zolmitriptan 5 mg 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.

What is in this leaflet

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1. What Zolmitriptan orodispersible tablets are and what they are used for

Zolmitriptan orodispersible tablets contain the active substance zolmitriptan and belong to a group of medicines called triptans.

Zolmitriptan orodispersible tablets are used to treat migraine headache with or without aura.

- 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 orodispersible tablets work 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 orodispersible tablets

DO NOT take Zolmitriptan orodispersible tablets if

- you are allergic to zolmitriptan, menthol or any of the other ingredients of this medicine (listed in section 6)
- 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: 'Other medicines and Zolmitriptan orodispersible 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 orodispersible 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
- 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 other medicine for treatment of depression (see 'Other medicines and Zolmitriptan orodispersible tablets' 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 over 65.

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 orodispersible tablets to correct the problem.

Children and adolescents

Zolmitriptan orodispersible tablets are not recommended in children and adolescents under 18 years.

Other medicines and Zolmitriptan orodispersible 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 triptans other than Zolmitriptan orodispersible tablets, leave 24 hours before taking this product.
- After taking Zolmitriptan orodispersible tablets leave 24 hours before taking triptans other than this product.
- 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

- Mono-amine oxidase inhibitors (MAOIs) such as moclobemide
- medicines called SSRIs (selective serotonin reuptake inhibitors) such as fluoxetine, paroxetine, sertraline or fluvoxamine
- medicines called SNRIs (serotonin norepinephrine reuptake inhibitors) such as venlafaxine, 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. If you already take a St. John's wort preparation, stop taking it and mention this to your doctor at your next visit.

Zolmitriptan orodispersible tablets with food and drink

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

- It is not known if taking zolmitriptan during pregnancy is harmful. Before taking Zolmitriptan orodispersible tablets, tell your doctor if you are pregnant or trying to become pregnant.
- Do not breast-feed within 24 hours of taking Zolmitriptan orodispersible tablets.

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 is unlikely to affect driving or using tools or machines. However, it is best to wait to see how this product affects you before you try these activities.

This medicine contains 2.53 mg sodium (less than 1 mmol sodium (23 mg)) per tablet, that is to say essentially 'sodium-free'.

3. How to take Zolmitriptan orodispersible 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 orodispersible tablets as soon as a migraine headache starts. You can also take it once an attack is underway.

- The recommended dose is one tablet (5 mg).
- 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 change your treatment.

Do not use more than the dose prescribed for you.

- Do not use more than two doses in one day. The maximum daily dose is 10 mg.

Method of administration

For oral use.

Place the tablet on your tongue, where it will dissolve and be swallowed with the saliva. You do not have to take a drink of water in order to swallow your tablet.

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 this medicine with you.

If you forget to take Zolmitriptan orodispersible 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.

Common side effects (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 heart beat
- feeling sick, vomiting
- stomach pain
- dry mouth
- muscle weakness or muscle pain
- feeling weak
- heaviness, tightness, pain or pressure in throat, neck, arms and legs or chest
- difficulty in swallowing

Uncommon side effects (may affect up to 1 in 100 people):

- very fast heart beat
- slightly higher blood pressure, increase in blood pressure only lasting a short time
- increase in the amount of water you pass (urine) or in how often you need to pass water

Rare side effects (may affect up to 1 in 1,000 people):

- allergic/hypersensitivity reactions including lumpy rash (hives) and swelling of the face, lips, mouth, tongue and throat. If you think that this product is causing an allergic reaction, stop using it and contact your doctor straight away

Very rare side effects (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. If you notice chest pain or shortness of breath after taking Zolmitriptan orodispersible tablets, contact your doctor and do not take any more.
- 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.
- feeling a sudden need to urinate (urinary urgency)

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 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 orodispersible tablets

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

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

Store in the original package in order to protect from moisture.

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 orodispersible tablets contain

The active substance is zolmitriptan.
Each orodispersible tablet contains 5 mg zolmitriptan.

- The other ingredients are:
- Mannitol
 - Maltodextrin
 - Microcrystalline cellulose
 - Crospovidone (type A)
 - Sodium hydrogen carbonate
 - Citric acid
 - Colloidal anhydrous silica
 - Saccharin sodium
 - Magnesium stearate
 - Menthol flavour (maltodextrin, natural menthol, modified maize starch)

What Zolmitriptan orodispersible tablets looks like and contents of the pack

Zolmitriptan orodispersible tablets are white, round and flat in shape orodispersible tablets, with a bevelled edge.
Zolmitriptan orodispersible tablets are packaged in oPA/Al/PVC-Al blisters containing 6 tablets.

Marketing Authorisation Holder

STADA, Linthwaite, Huddersfield, HD7 5QH, UK

Manufacturer

STADA M&D SRL, Str. Trascăului, nr. 10, Municipiul Turda, Judeţ Cluj, 401135, Romania

This leaflet was last revised in February 2025.