

Zolmitriptan 2.5 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

1. What Zolmitriptan 2.5mg orodispersible tablets are and what they are used for
2. What you need to know before you take Zolmitriptan 2.5mg orodispersible tablets
3. How to take Zolmitriptan 2.5mg orodispersible tablets
4. Possible side effects
5. How to store Zolmitriptan 2.5mg orodispersible tablets
6. Contents of the pack and other information

1. What Zolmitriptan 2.5mg orodispersible tablets are and what they are used for

Zolmitriptan 2.5mg orodispersible 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.

- This medicine 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 2.5mg orodispersible tablets

DO NOT take Zolmitriptan 2.5mg 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 2.5mg 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 before using this medicine 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 2.5mg orodispersible tablets' later in this section).

If you go into hospital tell the medical staff you are taking Zolmitriptan 2.5mg orodispersible tablets.

This medicine is not recommended for people under 18 years or 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 this medicine to correct the problem.

Other medicines and Zolmitriptan 2.5mg 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 2.5mg orodispersible tablets, leave 24 hours before taking this medicine.
- After taking Zolmitriptan 2.5mg orodispersible tablets leave 24 hours before taking triptans other than this medicine.
- If you take medicines containing ergotamine or ergot-type medicines (such as dihydroergotamine or methysergide), leave 24 hours before taking this medicine.
- After taking this medicine, 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, 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 may be more likely to happen.

Zolmitriptan 2.5mg orodispersible tablets with food and drink

You can take this medicine with or without food. It does not affect the way that zolmitriptan 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 this medicine, tell your doctor if you are pregnant or trying to become pregnant.
- Do not breast-feed within 24 hours of 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.
- This medicine is unlikely to affect driving or using tools or machines. However, it is best to wait to see how zolmitriptan affects you before you try these activities.

Sodium content

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

3. How to take Zolmitriptan 2.5mg orodispersible tablets

Always take this medicine exactly as your doctor 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 usual dose is one tablet (either 2.5 mg or 5 mg).
- 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.
- 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 2.5mg orodispersible tablets than you should

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

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 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 medicine 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 this medicine, **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 2.5mg 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 2.5mg orodispersible tablets contain

- The active substance is zolmitriptan.
One tablet contains 2.5 mg zolmitriptan.
- The other ingredients are:
 - Mannitol (Ph. Eur.)
 - 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 2.5mg orodispersible tablets look like and contents of the pack

Zolmitriptan 2.5mg orodispersible tablets are white, round and flat in shape orodispersible tablets, with a bevelled edge.

The tablets are packaged in Aluminium/Aluminium blister packs containing 2, 3, 6, 12 or 24 tablets or 2x1, 3x1, 6x1, 12x1 and 24x1 tablets in perforated unit dose blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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 September 2024.