**Package leaflet: Information for the patient**

# Zolmitriptan 2.5 mg orodispersible tablets 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:**


1. What Zolmitriptan is and what it is used for
2. What you need to know before you take Zolmitriptan
3. How to take Zolmitriptan
4. Possible side effects
5. How to store Zolmitriptan
6. Contents of the pack and other information


## 1. What Zolmitriptan is and what it is used for

Zolmitriptan contains zolmitriptan, which 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. You should not take Zolmitriptan to prevent migraines occuring.

## 2. What you need to know before you take Zolmitriptan

**Do not take Zolmitriptan:**

- if you are allergic to zolmitriptan or any of the other ingredients of this medicine (listed in section 6).
- if you have moderately high or very high blood pressure or mild uncontrolled high blood pressure.
- if you have or have had heart disease, a heart attack, or symptoms or signs of coronary heart disease, or angina (chest pain as a result of lack of oxygen in the heart muscle).
- if you have peripheral vascular disease (narrowing of the vessels that carry blood to the legs and arms).
- if you have had a stroke in the past or if you have had the symptoms of a stroke, which only lasted a short time and from which you made a complete recovery (transient ischaemic attack).
- if you are taking, or have taken in the last 24 hours, medicines containing ergotamine or ergotamine related medicines to treat migraine (including methysergide). See "Other medicines and Zolmitriptan" for further information.
- if you are taking, or have taken in the last 24 hours, any other triptans (such as naratriptan or sumatriptan). See 'Other medicines and Zolmitriptan' for further information.
- if you have severe problems with your kidney.
- you have a condition called Wolff-Parkinson-White syndrome.

Not to be taken for unusual forms of migraine caused by brain or eye problems.

**Warnings and precautions**
Talk to your doctor or pharmacist before taking Zolmitriptan if:

- you are at a higher risk of heart disease, for example: you are diabetic, a heavy smoker, you suffer from high blood pressure, you have too much fatty substances (lipids) in your blood or if there is a history of heart problems in your family. Your doctor should make additional checks, especially if you are a woman after menopause or a man older than 40 years old.
- you have ever had liver problems.
- you have abnormal heart rhythms.
- you are taking any other medicine for treatment of depression (see 'Other medicines and Zolmitriptan' later in this section).

**During treatment**
When taking this medicine, talk to your doctor or pharmacist if:

- you notice pain or a feeling of tightness in your chest and throat. If these symptoms don't pass quickly, tell your doctor immediately.
- your blood pressure becomes higher. Do not take more Zolmitriptan than it is recommended to help reduce the risk of this.
- you have headaches frequently despite the regular use of headache medicines.

**Other medicines and Zolmitriptan**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines bought without a prescription. In particular, inform your doctor if you are taking:

- Medicines for depression called selective serotonin re-uptake inhibitors (called SSRIs) e.g. fluoxetine or serotonin norepinephrine reuptake inhibitors (SNRIs) e.g. venlafaxine or duloxetine (which can also be used for some urinary problems).
- Moclobemide (a medicine used to treat depression and social phobia) because it may increase the effect of Zolmitriptan. If you take more than 150 mg moclobemide twice a day do not use Zolmitriptan.
- Cimetidine, fluvoxamine and quinolone antibiotics (such as ciprofloxacin) may increase the effect of Zolmitriptan therefore a maximum dose of 5 mg per day of Zolmitriptan is recommended.
- Medicines such as selegiline (a MAO-B inhibitor) because taking these medicines with Zolmitriptan may alter your mental state, or cause problems with your muscles. Your doctor will advise you whether Zolmitriptan is suitable for you.

Serotonin syndrome is a rare, life-threatening condition that has been reported in some patients who took zolmitriptan in combination with so called serotoninergic medicines (e.g. certain medicines for the treatment of depression). Signs of serotonin syndrome may be for example, agitation, tremor, restlessness, fever, excessive sweating, twitching, muscle rigidity uncoordinated movement of limbs or eyes and uncontrollable jerking of muscles. Your doctor may advise you on this.

**If you are taking or have taken other migraine medicines**
If you have taken another medicine for migraine such as ergotamine or ergotamine derivatives (e.g. methysergide) or another triptan (such as naratriptan or sumatriptan) you should wait for at least 24 hours before you take Zolmitriptan (see "Do not take Zolmitriptan").

If you have taken Zolmitriptan you should wait for at least 6 hours before taking ergotamine or ergotamine derivatives (e.g methysergide) and wait for at least 24 hours before taking another type of triptan medicine.

**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 or pharmacist for advice before taking this medicine.

**Pregnancy:** Do not take Zolmitriptan if you are pregnant, unless your doctor has told you that it is alright for you, even if you are pregnant.

**Breast-feeding:** Zolmitriptan may pass into breast milk. The amount the child could receive can be reduced if you avoid breast-feeding for 24 hours after taking Zolmitriptan.

**Driving and using machines**
This medicine, or a migraine, may make you feel drowsy. Do not drive or operate machinery if you feel drowsy after using Zolmitriptan.

**Zolmitriptan contains aspartame**
This medicine contains aspartame, a source of phenylalanine. May be harmful for people with phenylketonuria.

## 3. How to take Zolmitriptan

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Dosage**
The recommended dose is 2.5 mg to treat a migraine attack. Take this medicine as soon as possible after the start of the migraine attack. You can also take it when the migraine attack has already started.

If the symptoms of migraine return within 24 hours, you may take a second dose of Zolmitriptan. The second dose should not be taken within 2 hours of your first dose.

If you do not receive satisfactory relief from the symptoms of migraine using a dose of 2.5 mg of Zolmitriptan tell your doctor. They may consider increasing your dose to 5 mg per attack. You are more likely to suffer side effects with the higher dose (5 mg).

You should not take more than 2 doses of Zolmitriptan a day. The maximum daily dose is 10 mg Zolmitriptan.

**Use in elderly patients (over 65 years)**
The use of Zolmitriptan is not recommended.

**Patients with liver problems**
If you have moderate or serious problems with your liver you should not take more than 5 mg of Zolmitriptan in 24 hours. If you are not sure, check with your doctor who will advise you how much you can take.

**Patients with kidney problems**
If you have serious problems with your kidneys your doctor will tell you how much Zolmitriptan to take.

**Use in children and adolescents (under 17 years)**
Zolmitriptan should not be given to children and adolescents.

**Method and route of administration**
For oral use.
The tablet can be taken with or without food or liquid because the tablet dissolves on the tongue and can be swallowed. However Zolmitriptan will help to treat your migraine faster if you take the tablet with liquid.

1. Do not push the tablet through the packaging.
2. Hold the blister strip at the edges and separate one blister cell from the rest of the strip by gently tearing along the perforations around it.
3. Peel off the backing.
4. Carefully take out the tablet from the packaging (do not push it through).
5. Place the tablet on your tongue. Allow it to dissolve directly in your mouth and swallow it with saliva.



**If you take more Zolmitriptan than you should**
Contact your doctor or nearest hospital casualty department immediately. Take the container and any remaining tablets 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.

**Stop taking Zolmitriptan and tell your doctor straight away or go to your nearest hospital if you notice any of the following:**
- Serious allergic reactions, which may cause swelling of the face or the throat, difficulty breathing or dizziness or a nettle-like rash, hives
- Heart attack (you may have severe chest pain, feel clammy, short of breath or have pain in the jaw and arms); chest pain (angina)
- Insufficient flow of blood to the gut, intestines or spleen (which may present as bloody diarrhoea or abdominal pain)

**Other side effects include:**

**Common side effects** (may affect up to 1 in 10 people):
- Dizziness; headache, increased sensitivity to touch, tingling, pins and needles; sleepiness; warm sensation; unusual or altered sensations
- An irregular heart rhythm or missed beats
- Abdominal pain, feeling sick; vomiting; dry mouth; difficulty swallowing (dysphagia)
- Muscle weakness or muscle pain; general weakness; a feeling of heaviness or tightness, pain or pressure in throat, neck, limbs or chest

**Uncommon side effects** (may affect up to 1 in 100 people):
- Increased heart beat
- An increase in blood pressure, which may also occur soon after taking the tablets, but only lasting a short time
- Passing abnormally large amounts of urine; urinating more frequently

**Very rare side effects** (may affect up to 1 in 10,000 people):
- Feeling the need to urinate urgently

**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

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 label and the carton or on the bottle after "EXP". The expiry date refers to the last day of that month.

Store below 30°C.
Blister packs - Store in the original package in order to protect from moisture.

Blister packs in pouch - Store in the original package in order to protect from moisture. After first opening the pouch, use within 90 days.

Bottle packs – Keep the bottle tightly closed in order to protect from moisture. After first opening the bottle, use within 100 days.

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 contains:**
- The active substance is zolmitriptan Zolmitriptan 2.5 mg: Each orodispersible tablet contains 2.5 mg of zolmitriptan. Zolmitriptan 5 mg: Each orodispersible tablet contains 5 mg of zolmitriptan.
- The other ingredients are: mannitol, silica colloidal anhydrous, crospovidone (Type A), crospovidone (Type B), aspartame (E951), cellulose microcrystalline, guar gum, magnesium stearate; orange flavour (contains orange flavour, maize maltodextrin, alpha tocopherol (E307))

**What Zolmitriptan looks like and contents of the pack**
The 2.5 mg orodispersible tablets are white to off-white, round, flat faced bevelled edged orodispersible tablet marked with **"M"** on one side and **"ZT1"** on the other side.

The 5 mg orodispersible tablets are white to off-white, round, flat faced bevelled edged tablet marked with **"M"** on one side and **"ZT3"** on the other side.

This medicine is available in blister packs of 2, 3, 4, 5, 6, 10, 12, 18, 20, 24 or 48 tablets or in perforated unit dose blister pack sizes of 6 x 1 or 12 x 1 or 24 x 1 or 48 x 1 orodispersible tablets. The blisters may be placed in a triple laminated pouch with desiccant bags (do not eat the desiccant).
or
a bottle pack with desiccant (do not eat the desiccant) and absorbent cotton in pack sizes of 100 orodispersible tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**
Mylan,
Potters Bar,
Hertfordshire,
EN6 1TL,
United Kingdom.

**Manufacturer**
Gerard Laboratories,
35/36 Baldoyle Industrial Estate,
Grange Road,
Dublin 13,
Ireland.

Mylan Hungary Kft.
H-2900 Komárom,
Mylan utca 1,
Hungary.

**This leaflet was last revised in July 2023**

Mylan
ART-4810-05
75097854