

**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**

The name of your medicine is Zolmitriptan 2.5 mg orodispersible tablets or Zolmitriptan 5 mg orodispersible tablets (called Zolmitriptan throughout this leaflet).

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

Zolmitriptan is used to **treat migraine attacks** (headaches and nausea).

Migraine symptoms may be caused by swollen blood vessels in the head. Zolmitriptan reduces 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**

**Do not take Zolmitriptan**

- if you are allergic (hypersensitive) to zolmitriptan or any of the other ingredients of this medicine (listed in section 6).
- if you have high blood pressure.
- if 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.
- if you have circulatory problem (restricted blood flow in your legs or arms)
- if you have had a stroke or short-lasting symptoms similar to stroke (transient ischaemic attack or TIA).
- if you have severe kidney problems (creatinine clearance of less than 15ml/min)
- if 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 (see "Other medicines and Zolmitriptan").

Do not take Zolmitriptan if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Zolmitriptan.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Zolmitriptan

- 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.
- if you have ever had liver problems.
- if you have headaches which are not like your usual migraine headache.
- if you have been told that you have Wolff-Parkinson-White syndrome (a type of abnormal heart beat).
- if you are taking the herbal remedy called St. John's Wort (see "Other medicines and Zolmitriptan").

The use of Buprenorphine together with zolmitriptan can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Zolmitriptan").

Zolmitriptan is not recommended for patients 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 taking Zolmitriptan to correct the problem.

**Other medicines and Zolmitriptan**

Tell your doctor or pharmacist if you are taking or have recently taken or might have taken any other medicines.

**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 another triptan.
- 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.

Some medicines may increase the side effects of zolmitriptan and may sometimes cause very serious reactions. Do not take any other medicines whilst taking zolmitriptan without first talking to your doctor, especially:

- **buprenorphine/opioids.** These medicines may interact with zolmitriptan and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

**Zolmitriptan 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**

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.

It is not known if taking zolmitriptan during pregnancy is harmful.

Therefore it should be used during the pregnancy only if the potential benefit to the mother outweighs the potential risk to the unborn child and no other appropriate treatment option is available.

No data exists on the excretion of zolmitriptan into breast milk. Therefore, as a precautionary measure, breast-feeding should be avoided for 24 hours after treatment.

**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.

**Important information about the ingredients of Zolmitriptan**

This medicine contains 2.5/5 mg aspartame in each 2.5/5 mg orodispersible tablet. Aspartame is a source of phenylalanine It maybe harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly. 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**

Always take this medicine exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

**Zolmitriptan is used to treat migraine attacks. Take Zolmitriptan as soon as possible after your migraine headache has started. You can also take it once an attack is underway.**

**Do not use it to prevent an attack.**

**How much to take**

Do not use more than the dose prescribed for you.

**Adults (aged over 18 years and under 65 years)**

The usual starting dose is 2.5 mg of zolmitriptan. If a 2.5 mg dose did not give you enough help with your migraine, tell your doctor. Your doctor may change your treatment and recommend you take a 5mg dose for your next attack. Occurrence of side effects is more likely with higher doses.

The maximum daily dose is 10mg zolmitriptan.

**Special patient groups**

**Patients aged over 65 years**

Zolmitriptan should not be given to patients over 65 years.

**Patients with liver problems**

If you have liver problems, the recommended maximum daily dose is lowered to 5mg.

**Patients with kidney problems**

Your dosage can be the same as in adults.

**Children and adolescents under 18 years of age**

Zolmitriptan should not be given to children or adolescents under 18 years of age.

**Taking this medicine**

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

**If after 2 hours after taking Zolmitriptan you still have migraine or migraine returns within 24 hours you can take another tablet**  
**Do not take more than 2 doses of Zolmitriptan in a 24-hour period (more than**



**two 2.5 mg or 5 mg doses in a 24-hour period – according to your prescribed dose).**

**Always wait at least 2 hours between doses.**

If the tablets did not give you enough help with your migraine, tell your doctor. Your doctor may change your treatment.

If your condition worsens, seek medical attention.

**If you take more Zolmitriptan than you should**

If you take more tablets than you should or someone accidentally swallows some, contact your doctor or go to the nearest hospital straight away. Take the medicine pack and any remaining tablets with you so that the doctor knows what has been taken.

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 experience any of the side effects listed below stop taking the medication and seek the doctor immediately**

**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.

**The following side-effects have also been seen:**

**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 heart beat.
- 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.
- Difficulty in swallowing (dysphagia).

**Uncommon** (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.

#### 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](http://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 package. The expiry date refers to the last day of that month.

This medicinal product doesn't require any special temperature storage conditions.

Store in the original inner package (blister) 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 to protect the environment.

#### 6. CONTENTS OF THE PACK AND OTHER INFORMATION

**What Zolmitriptan orodispersible tablets contain**

**2.5 mg orodispersible tablets:** The active substance is zolmitriptan 2.5 mg per each tablet.

The other ingredients are: mannitol, cellulose microcrystalline, aspartame, croscarmellose sodium, silica colloidal anhydrous, magnesium stearate, orange powder flavour; (maltodextrin, thickener gum arabic (acacia gum) (E414), vegetable oil, antioxidant butylated hydroxyanisole (BHA) (E320), antioxidant alpha-tocopherol (E307).

**5 mg orodispersible tablets:** The active substance is zolmitriptan 5mg per each tablet.

The other ingredients are: mannitol, cellulose microcrystalline, aspartame, orange flavour (maltodextrin, acacia gum E414, ascorbic acid E300, butylated hydroxyanisole E320), croscarmellose sodium, silica colloidal anhydrous, magnesium stearate.

**What Zolmitriptan orodispersible tablets looks like and contents of the pack.**

**2.5 mg orodispersible tablets:** White to off-white, round, flat faced bevelled edge uncoated tablet with "2.5" debossed on one side and plain on other side.

**5 mg orodispersible tablets:** White to off white round biconvex uncoated tablets with deep breakline on one side and plain on other side. The tablet can be divided into equal halves.

**Size of packing**

Zolmitriptan 2.5 mg orodispersible tablets: 2, 3, 6, 7, 10, 12, 14, 18.

Zolmitriptan 5 mg orodispersible tablets: 2, 3, 6, 7, 10, 12, 14, 18.

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder

Zentiva Pharma UK Limited,  
12 New Fetter Lane,  
London,  
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#### Manufacturer(s)

##### **2.5 mg orodispersible tablets**

Saneca Pharmaceuticals a.s.  
Nitrianska 100  
920 27 Hlohovec  
Slovak Republic

##### **5 mg orodispersible tablets**

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