

PACKAGE LEAFLET:
INFORMATION FOR THE USER

**Zolmitriptan 2.5 mg
film-coated tablets**

**Zolmitriptan 5 mg
film-coated tablets**

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 is and what it is used for
2. Before you take Zolmitriptan
3. How to take Zolmitriptan
4. Possible side effects
5. How to store Zolmitriptan
6. Further information

1. WHAT ZOLMITRIPTAN IS AND WHAT IT IS USED FOR

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

Zolmitriptan film-coated tablets contains the active substance zolmitriptan and belongs to a group of medicines called triptans.

Zolmitriptan is used to **treat migraine attacks** (headache 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. BEFORE YOU TAKE ZOLMITRIPTAN

Do not take Zolmitriptan if you

- are allergic (hypersensitive) to zolmitriptan or any of the other ingredients of this medicine (see Section 6: Further information).
- have high blood pressure.
- 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.
- have circulatory problem (restricted blood flow in your legs or arms)
- have had a stroke or short-lasting symptoms similar to stroke (transient ischaemic attack or TIA).
- have been told that you have Wolff-Parkinson-White Syndrome (a type of abnormal heart beat).
- have severe kidney problems (creatinine clearance of less than 15ml/min)
- 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 section below: 'Taking other medicines').

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.

Take special care with Zolmitriptan

Before you take Zolmitriptan, 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.
- have ever had liver problems.
- have headaches which are not like your usual migraine headache.
- are taking any medicine for treatment of depression or the herbal remedy called St. John's wort (see section below: 'Taking other medicines').

Zolmitriptan is not recommended for people aged 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.

Taking or using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

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.

Taking 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

Ask your doctor or pharmacist for advice before taking any medicine. Before taking this medicine, tell your doctor if you are pregnant, trying to become pregnant or breast-feeding. 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.

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.

3. HOW TO TAKE ZOLMITRIPTAN

Always take Zolmitriptan exactly as your doctor has told you.

You should 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 one 2.5 mg tablet. If 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 5 mg dose for your next attack.

Occurrence of side effects is more likely with higher doses.

The maximum daily dose is 10 mg.

Special patient groups

People aged over 65 years

Zolmitriptan should not be given to patients over 65 years.

People with liver problems

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

People 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

- Swallow your tablet with a drink of water.
- You can take Zolmitriptan with or without food. It does not affect the way that Zolmitriptan works.

If 2 hours after taking Zolmitriptan you still have migraine or migraine returns within 24 hours you can take another tablet.

You can take another tablet if the migraine is still present after two hours or if it returns within 24 hours.

Do not take more than 2 doses of Zolmitriptan in a 24-hour period (more than two 2.5 mg or 5mg 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Zolmitriptan 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 see a doctor immediately

- rare: affects 1 to 10 users in 10,000
 - Allergic reactions including itchy rash (urticaria) and swelling of the face, lips, mouth, tongue and throat.
- very rare: affects less than 1 user in 10,000
 - 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: affects 1 to 10 users in 100
 - 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.

- uncommon: affects 1 to 10 users in 1,000
 - 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.

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.

5. HOW TO STORE ZOLMITRIPTAN

Keep out of the reach and sight of children. Do not use Zolmitriptan 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.

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 film-coated tablets contain

2.5 mg film-coated tablets: The active substance is zolmitriptan 2.5 mg per tablet.

5 mg film-coated tablets: The active substance is zolmitriptan 5 mg per tablet.

The other ingredients are

Tablet core: mannitol, cellulose microcrystalline, croscarmellose sodium, silica colloidal anhydrous, magnesium stearate

Tablet coating:

2.5 mg film-coated tablets: Opadry Yellow 02G82587#: Hypromellose (E 464), Titanium Dioxide (E 171), Macrogol 400, Macrogol 8000, Iron oxide yellow (E 172).

5 mg film-coated tablets: Opadry Pink 02G84574#: Hypromellose (E 464), Titanium Dioxide (E 171), Macrogol 400, Macrogol 8000, Iron oxide red (E 172).

What Zolmitriptan film-coated tablets looks like and contents of the pack

2.5 mg film-coated tablets: Yellow, round shaped, biconvex film coated tablets with "2.5" debossed on one side and plain on other side.

5 mg film-coated tablets: Pink, round shaped, biconvex film coated tablets with deep break line on one side and plain on other side. The tablet can be divided into equal halves.

Size of packing

2, 3, 6, 7, 12, 14, 18

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Zentiva, One Onslow Street, Guildford, Surrey, GU1 4YS, UK

Manufacturer

S.C. Zentiva S.A
Theodor Pallady Nr 50,
032266 Bucharest,
Romania

This leaflet was last approved in November 2011.