Patient Information
Zolmitriptan Orally Disintegrating Tablets

Please read this information before you start taking zolmitriptan and each time you renew your prescription just in case anything has changed. Remember, this summary does not take the place of discussions with your doctor. You and your doctor should discuss zolmitriptan when you start taking your medication and at regular checkups.

Phenylketonurics
Phenylketonurics is a component of aspartame. Each 2.5 mg zolmitriptan orally disintegrating tablet contains 2.51 mg phenylalanine. Each 5 mg zolmitriptan orally disintegrating tablet contains 5.01 mg phenylalanine.

What is zolmitriptan?
Zolmitriptan is a prescription medication used to treat migraine headaches in adults. Zolmitriptan is not for other types of headaches. The safety and efficacy of zolmitriptan in patients under 18 have not been established.

What is a Migraine Headache?
Migraine is an intense, throbbing headache. You may have pain on one or both sides of your head. You may have nausea and vomiting, and be sensitive to light and noise. The pain and symptoms of a migraine headache can be worse than a common headache. Some women get migraines around the time of their menstrual period. Some people have visual symptoms before the headache, such as flashing lights or wavy lines, called an aura.

How does zolmitriptan work?
Treatment with zolmitriptan reduces swelling of blood vessels surrounding the brain. This swelling is associated with the headache pain of a migraine attack. Zolmitriptan blocks the release of substances from nerve endings that cause more pain and other symptoms like nausea, and sensitivity to light and sound. It is thought that these actions contribute to relief of your symptoms by zolmitriptan.

Who should not take zolmitriptan? Do not take zolmitriptan if you:
- Have heart disease or a history of heart disease
- Have uncontrolled high blood pressure
- Have hemiplegic or basilar migraine (if you are not sure about this, ask your doctor)
- Have or had a stroke or problems with your blood circulation
- Have serious liver problems
- Have taken any of the following medicines in the last 24 hours: other “triptans” like almotriptan (AXERT®), eletriptan (RELAPAX®), frovatriptan (FROVA®), naratriptan (AMERGE®), rizatriptan (MAXALT®), sumatriptan (IMITREX®), sumatriptan/naproxen (TREXIMET®); ergotamines like BELLERGAL-S®; CAFERGOT®; ERGOMAR®; WIGRAINE®; dihydroergotamine like D.H.E. 45® or MIGRANAL®; or methysergide (SANSERT®). These medications have side effects similar to zolmitriptan.
- Have taken monoamine oxidase (MAO) inhibitors such as phenelzine sulfate (NARDIL®) or tranylcypromine sulfate (PARNATE®) for depression or other conditions within the last 2 weeks.
- Are allergic to zolmitriptan or any of its ingredients. The active ingredient is zolmitriptan. The inactive ingredients are listed at the end of this leaflet.

Tell your doctor about all the medicines you take or plan to take, including prescription and non-prescription medicines, supplements, and herbal remedies.

Tell your doctor if you are sensitive to phenylalanine, which can be found in the artificial sweetener aspartame. Zolmitriptan orally disintegrating tablets contain phenylalanine.

Tell your doctor if you are taking selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs), two types of drugs for depression or other disorders. Common SSRIs are CELEXA® (citalopram HBr), LEXAPRO® (escitalopram oxalate), PAXIL® (paroxetine), PROZAC® (fluoxetine), SYMBYAX® (olanzapine/fluoxetine), ZOLOFT® (sertraline), SARAFEM® (fluoxetine) and LUVOX® (fluvoxamine). Common SNRIs are CYMBALTAX® (duloxetine) and EFFEXOR® (venlafaxine). Your doctor will decide if you can take zolmitriptan with your other medicines.

Tell your doctor if you know that you have any of the following: risk factors for heart disease like high cholesterol, diabetes, smoking, obesity (overweight), menopause, or a family history of heart disease or stroke.

Tell your doctor if you are pregnant, planning to become pregnant, breastfeeding, planning to breastfeed, or not using effective birth control.

How should I take zolmitriptan?
- Take zolmitriptan exactly as your doctor tells you to take it. Your doctor will tell you how much zolmitriptan to take and when to take it.
- If you take zolmitriptan oral disintegrating tablets, do not remove the tablet from the blister pack until you are ready to take your medicine.
- You do not need to take any liquids with your zolmitriptan oral disintegrating tablets.
- Take zolmitriptan orally disintegrating tablets whole.
- Place zolmitriptan oral disintegrating tablets on your tongue, where it will dissolve.
- Safely throw away any unused tablets or pieces of tablets that have been removed from the blister packaging.
• If your headache comes back after your first dose, you may take a second dose anytime after 2 hours of taking the first dose. For any attack where the first dose did not work, do not take a second dose without talking with your doctor. Do not take more than a total of 10 mg of zolmitriptan (tablets or spray combined in any 24 hour period. If you take too much medicine, contact your doctor, hospital emergency department, or poison control center right away.

What are the possible side effects of zolmitriptan?
Zolmitriptan is generally well tolerated. As with any medicine, people taking zolmitriptan may have side effects. The side effects are usually mild and do not last long.
The most common side effects of zolmitriptan are:
• Pain, pressure or tightness in the neck, throat or jaw
• dizziness
• tingling or other abnormal sensations
• tiredness
• drowsiness
• feeling warm or cold
• nausea
• feeling of tightness or heaviness in other areas of the body
• dry mouth

In very rare cases, patients taking triptans may experience serious side effects, such as heart attacks, high blood pressure, stroke, or serious allergic reactions. Extremely rarely, patients have died. Call your doctor right away if you have any of the following problems after taking zolmitriptan:
• severe tightness, pain, pressure or heaviness in your chest, throat, neck, or jaw
• shortness of breath or wheezing
• sudden or severe stomach pain
• hives; tongue, mouth, or throat swelling
• problems seeing
• unusual weakness or numbness

Some people may have a reaction called serotonin syndrome, which can be life-threatening, when they use zolmitriptan. In particular, this reaction may occur when they use zolmitriptan together with certain types of antidepressants known as SSRIs or SNRIs. Symptoms may include mental changes (hallucinations, agitation, coma), fast heartbeat, changes in blood pressure, high body temperature or sweating, tight muscles, trouble walking, nausea, vomiting, and diarrhea. Call your doctor immediately if you have any of these symptoms after taking zolmitriptan.

This is not a complete list of side effects. Talk to your doctor if you develop any symptoms that concern you.

What to do in case of an overdose?
Call your doctor or poison control center or go to the nearest hospital emergency room.

General advice about zolmitriptan
Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use zolmitriptan for a condition for which it was not prescribed. Do not give zolmitriptan to other people, even if they have the same symptoms as you. People may be harmed if they take medicines that have not been prescribed for them.

This leaflet summarizes the most important information about zolmitriptan. If you would like more information about zolmitriptan, talk to your doctor. You can ask your doctor or pharmacist for information on zolmitriptan that is written for healthcare professionals.

Please address medical inquiries to, (MedicalAffairs@zydususa.com) Tel.: 1-877-993-8779.

What are the ingredients in zolmitriptan orally disintegrating tablets?
Active ingredient: zolmitriptan
Inactive ingredients: anhydrous citric acid, aspartame, colloidal silicon dioxide, crospovidone, gelatin, magnesium stearate, mannitol, microcrystalline cellulose, orange flavor, polacrilin potassium and sodium stearyl fumarate.

Store zolmitriptan orally disintegrating tablets at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature] and away from children. Protect from light and moisture. Discard when expired.

Other brands mentioned are trademarks of their respective owners.