

Patients should be informed that ZOMIG may cause serious cardiovascular side effects such as myocardial infarction or stroke, which may result in hospitalization and even death. Although serious cardiovascular events can occur without warning symptoms, patients should be alert for the signs and symptoms of chest pain, shortness of breath, weakness, slurring of speech, and should ask for medical advice when observing any indicative sign or symptoms. Patients should be apprised of the importance of this follow-up [see *Warnings and Precautions (5.1, 5.3, 5.4)*].

17.2 Serotonin Syndrome

Patients should be cautioned about the risk of serotonin syndrome with the use of ZOMIG or other triptans, particularly during combined use with selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs) [See *Warnings and Precautions (5.5)*].

17.3 Device Use

The ZOMIG Nasal Spray device is packaged in a carton and is a blue colored plastic device with a gray protection cap, labeled to indicate the nominal dose. Patients should be cautioned to not remove the gray protection cap until prior to dosing. The ZOMIG Nasal Spray device is placed in a nostril and actuated to deliver a single dose. **Patients should be cautioned to avoid spraying the contents of the device in their eyes.**

17.4 Pregnancy

ZOMIG should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus.

17.5 Approved Patient Labeling

Please read this information before you start taking ZOMIG Nasal Spray 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 ZOMIG Nasal Spray when you start taking your medication and at regular checkups.

What is ZOMIG Nasal Spray?

ZOMIG Nasal Spray is a prescription medication used to treat migraine headaches in adults. ZOMIG Nasal Spray is not for other types of headaches. The safety and efficacy of ZOMIG 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 ZOMIG Nasal Spray work?

Treatment with ZOMIG Nasal Spray reduces swelling of blood vessels surrounding the brain. This swelling is associated with the headache pain of a migraine attack. ZOMIG Nasal Spray 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 ZOMIG Nasal Spray.

Who should not take ZOMIG Nasal Spray?

Do not take ZOMIG Nasal Spray 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 (RELPAX[®]), 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 ZOMIG Nasal Spray.
- Have taken monoamine oxidase (MAO) inhibitors such as phenelzine sulfate (NARDIL[®]) or tranylcypromine sulfate (PARNATE[®]) for depression or other conditions, or if it has been less than 2 weeks since you stopped taking a MAO inhibitor.
- Are allergic to ZOMIG Nasal Spray 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 nonprescription medicines, supplements, and herbal remedies.

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 CYMBALTA[®] (duloxetine) and EFFEXOR[®] (venlafaxine). Your doctor will decide if you can take ZOMIG Nasal Spray 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, breast feeding, planning to breast feed, or not using effective birth control.

How should I take ZOMIG NASAL Spray?

The ZOMIG Nasal Spray device is a blue colored plastic sprayer device with a gray protection cap, labeled to indicate the dose. For adults, the usual dose is a single nasal spray taken into one nostril. 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 didn't work, do not take a second dose without talking with your doctor. Do not take more than a total of 10 mg of ZOMIG (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.

The ZOMIG Nasal Spray device consists of the following parts:

- A. **The Tip:** This is the part that you put into your nostril. The medicine comes out of a tiny hole in the top.
- B. **The Protective Cap:** This covers the tip to protect it. Do not remove the protective cap until just before you are ready to take your ZOMIG Nasal Spray.
- C. **The Finger-grip:** This is the part that you hold when you use the sprayer.
- D. **The Plunger:** This is the part that you press when you put the tip into your nostril. This sprayer works only once.

Steps for using ZOMIG Nasal Spray (Please read all steps before using for the first time):

1. Blow your nose gently before use. Remove the protective cap (B) (Figure 1). Hold the nasal sprayer device gently with your fingers and thumb as shown in the picture to the right (Figure 2). There is only one dose in the nasal sprayer. Do not try to prime the nasal sprayer or you will lose the dose. Do not press the plunger until you have put the tip into your nostril or you will lose the dose.

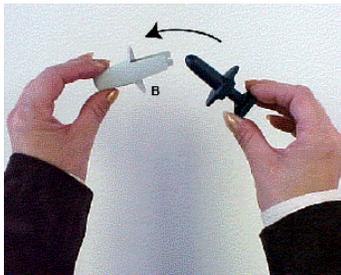


Figure 1

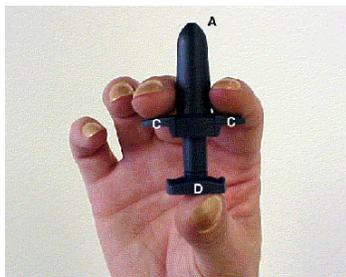


Figure 2

2. Block one nostril by pressing firmly on the side of your nose (Figure 3). Either nostril can be used. Put the tip (A) of the sprayer device into the other nostril as far as feels comfortable and tilt your head slightly as shown in the picture to the right (Figure 4).

Do not press the plunger yet.

Do not spray the contents of the device in your eyes.



Figure 3



Figure 4

3. Breathe in gently through your nose and at the same time press the plunger (D) firmly with your thumb. The plunger may feel stiff and you may hear a click. Keep your head slightly tilted back and remove the tip from your nose. Breathe gently through your mouth for 5-10 seconds. You may feel liquid in your nose or the back of your throat. This is normal and will soon pass.

What are the possible side effects of ZOMIG Nasal Spray?

ZOMIG Nasal Spray is generally well tolerated. As with any medicine, people taking ZOMIG Nasal Spray may have side effects. The side effects are usually mild and do not last long.

The most common side effects of ZOMIG Nasal Spray are:

- unusual taste, dry mouth
- tingling sensation, skin sensitivity, especially around the nose
- pain, pressure, and tightness sensations (eg, in the nose, throat, or chest)
- drowsiness, weakness, dizziness
- nausea

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 ZOMIG Nasal Spray:**

- **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 ZOMIG. In

particular, this reaction may occur when they use ZOMIG 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, diarrhea. Call your doctor immediately if you have any of these symptoms after taking ZOMIG.

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 ER.

General advice about ZOMIG Nasal Spray

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use ZOMIG Nasal Spray for a condition for which it was not prescribed. Do not give ZOMIG Nasal Spray 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 ZOMIG Nasal Spray. If you would like more information about ZOMIG Nasal Spray, talk to your doctor. You can ask your doctor or pharmacist for information on ZOMIG Nasal Spray that is written for health professionals. You can also call 1-800-236-9933 or visit our web site at www.ZOMIG.com.

What are the Ingredients in ZOMIG Nasal Spray?

Active ingredient: zolmitriptan

Inactive ingredients: anhydrous citric acid, dibasic sodium phosphate, and purified water

Store your medication at controlled room temperature, 20-25°C (68-77°F), and away from children. Discard after use or when it expires.

ZOMIG is a registered trademark of the AstraZeneca group of companies.

Other brands mentioned are trademarks of their respective owners and are not trademarks of the AstraZeneca group of companies. The makers of these brands are not affiliated with AstraZeneca or its products.

Manufactured for:
AstraZeneca Pharmaceuticals LP
Wilmington, Delaware 19850
By: AstraZeneca UK Limited, Macclesfield,
Cheshire UK

Made in the United Kingdom

31245-XX