

PATIENT SUMMARY OF INFORMATION

RELPA[®] (eletriptan hydrobromide)

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

What is RELPAX?

RELPA[®] is a prescription medicine used to treat migraine headaches in adults. RELPA[®] is not for other types of headaches.

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 RELPAX Work?

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

Who should not take RELPAX?

Do not take RELPAX if you:

- have uncontrolled high blood pressure.
- have heart disease or a history of heart disease.
- 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” or triptan combination products such as almotriptan (Axert[®]), frovatriptan (Frova[™]), naratriptan (Amerge[®]), rizatriptan (Maxalt[®]), sumatriptan (Imitrex[®]) sumatriptan and naproxen sodium, (Treximet[™]), zolmitriptan (Zomig[®]); ergotamines like Bellergal-S[®], Cafergot[®], Ergomar[®], Wigraine[®]; dihydroergotamine like D.H.E. 45[®] or Migranal[®]; or methysergide (Sansert[®]). These medicines have side effects similar to RELPAX.*
- have taken the following medicines within at least 72 hours: ketoconazole (Nizoral[®]), itraconazole (Sporanox[®]), nefazodone (Serzone[®]), troleandomycin (TAO[®]), clarithromycin (Biaxin[®]), ritonavir (Norvir[®]), and nelfinavir (Viracept[®]). These medicines may cause an increase in the amount of RELPAX in the blood.*
- are allergic to RELPAX or any of its ingredients. The active ingredient is eletriptan. 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. Your doctor will decide if you can take RELPAX with your other medicines.

Some medicines used in treating depression such as the selective serotonin reuptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs) may cause a condition called

serotonin syndrome especially during combined use with certain migraine medications. Your doctor needs to know if you are taking any of these medicines, when taking Relpax.

- 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®/SARAFEM® (fluoxetine), SYMBYAX® (olanzapine/fluoxetine), ZOLOFT® (sertraline), and fluvoxamine. Common SNRIs are CYMBALTA® (duloxetine) and EFFEXOR® (venlafaxine).

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

How should I take RELPAX?

RELPAX comes in 20 mg and 40 mg tablets. When you have a migraine headache, take your medicine as directed by your doctor.

- Take one RELPAX Tablet as soon as you feel a migraine coming on.
- If your headache improves and then comes back after 2 hours, you can take a second tablet.
- If the first tablet did not help your headache at all, do not take a second tablet without talking with your doctor.
- Do not take more than two RELPAX Tablets in any 24-hour period.

What are the possible side effects of RELPAX?

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

The most common side effects of RELPAX are:

- dizziness
- nausea
- weakness
- tiredness
- pain or pressure sensation (e.g., in the chest or throat)

In very rare cases, patients taking triptans, such as RELPAX, may experience serious side effects, including heart attacks. **Call your doctor right away** if you have:

- severe chest pains
- shortness of breath

Some patients taking triptans may have a reaction called serotonin syndrome particularly during combined use with certain types of antidepressants, SSRIs or SNRIs. Symptoms may include confusion, hallucinations, fast heart beat, feeling faint, fever, sweating, muscle spasm, difficulty walking and/or diarrhea. Call your doctor right away if you have any of these symptoms after taking RELPAX.

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 RELPAX

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use RELPAX for a condition for which it was not prescribed. Do not give RELPAX to other people, even if they have the same symptoms you have.

This leaflet summarizes the most important information about RELPAX. If you would like more information about RELPAX, talk with your doctor. You can ask your doctor or pharmacist for information on RELPAX that is written for health professionals. You can also call 1-866-4RELPAX (1-866-473-5729) or visit our web site at www.RELPAX.com.

What are the ingredients in RELPAX?

Active ingredient: eletriptan hydrobromide
Inactive ingredients: microcrystalline cellulose, lactose, croscarmellose sodium, magnesium stearate, titanium oxide, hypromellose, triacetin, and FD&C Yellow No. 6 aluminum lake.

Store RELPAX Tablets at room temperature 15-30°C (59-86°F).

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Rx only

