PART III: CONSUMER INFORMATION

PrRELPAX®
(eletriptan hydrobromide tablets)

This leaflet is part III of a three-part "Product Monograph" published when RELPAX was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about RELPAX. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
The name of your medicine is RELPAX. This medicine is one of a group of antimigraine drugs called 5-HT_1 agonists.

RELPAX is intended to relieve your migraine headache and other associated symptoms of a migraine attack.

What it does:
Migraine headache is believed to be caused by a widening of the blood vessels in the head. RELPAX narrows the vessels and relieves the pain and other symptoms of migraine headache

When it should not be used:
RELPAX should not be used continuously to prevent or reduce the number of attacks you experience. Use RELPAX only to treat an actual migraine headache attack. RELPAX should not be used to relieve pain other than that associated with migraine headache.

Do not take RELPAX if you:
- are allergic to any of the ingredients (see **What the medicinal ingredient is** and **What the nonmedicinal ingredients are** sections)
- have uncontrolled or severe high blood pressure
- have heart disease or history of heart disease
- have severe liver disease
- have or had a stroke or problems with your blood circulation, Raynaud syndrome or transient ischemic attacks (TIAs)
- have taken any of the following medicines in the last 72 hours: ketoconazole, itraconazole, nefazodone, troleandomycin, clarithromycin, ritonavir, and nelfinavir? These medicines may cause an increase in the amount of RELPAX in the blood, increasing the risk of serious side effects.
- have taken the following medicines in the last 24 hours: other "triptans" like almotriptan, sumatriptan, naratriptan, zolmitriptan, rizatriptan or ergotamine-type medications such as ergotamine, dihydroergotamine or methysergide. These medicines are of the same class as RELPAX, and taking them together increases the risk of serious side effects.

Do not use RELPAX if you are pregnant, think you might be pregnant, are trying to become pregnant or are using inadequate contraception, unless you have discussed this with your physician.

What the medicinal ingredient is:
Eletriptan hydrobromide

What the nonmedicinal ingredients are:
Each tablet also contains the following inactive ingredients: croscarmellose sodium, FD & C Yellow No 6 aluminum lake, hypromellose, lactose monohydrate, microcrystalline cellulose, magnesium stearate, titanium dioxide and triacetin.

Lactose-intolerant Patients: You should be aware that this product contains lactose.

What dosage forms it comes in:
RELPAX tablets for oral administration are orange, round film-coated tablets and contain 20 or 40 mg of eletriptan base**.**

WARNINGS AND PRECAUTIONS

The decision to use RELPAX is one that you and your doctor should make jointly, taking into account your individual preferences and medical circumstances. If you have risk factors for heart disease (such as high blood pressure, high cholesterol, obesity, diabetes, smoking, strong family history of heart disease, or you are a postmenopausal female or a male over 40), you should tell your doctor. Your doctor should evaluate you for heart disease in order to determine if RELPAX is appropriate for you.

Important Questions to Consider Before Taking RELPAX**:** If the answer to any of the following questions is **yes**, or if you do not know the answer, then please speak with your doctor before you take any RELPAX.

- Are you pregnant? Do you think you might be pregnant? Are you trying to become pregnant? Are you using inadequate contraception? Are you breast-feeding?
- Do you experience or have you ever experienced any pain or tightness in the chest, (which may or may not spread to your neck, jaw, or upper arm), shortness of breath, rapid heartbeats or irregular heartbeats? Do you have angina?
- Have you ever had heart or blood vessel disease? Have you had a heart attack or stroke? Have you ever had Raynaud syndrome or transient ischemic attacks (TIAs)?
- Do you have risk factors for heart disease, such as: high blood pressure, high cholesterol, smoking, obesity, diabetes, or strong family history of heart disease? Are you postmenopausal, or a male over 40?
- Have you ever had to stop taking this or any other medication because of an allergy or other problems?
- Are you taking any other migraine 5-HT_1 agonist medications such as almotriptan, sumatriptan succinate/sumatriptan, naratriptan as naratriptan hydrochloride, zolmitriptan,

rizatriptan benzoate or migraine medications containing ergotamine, dihydroergotamine, or methysergide?
- Are you taking any medications for depression such as selective serotonin reuptake inhibitors (SSRIs) such as sertraline, escitalopram and fluoxetine, or serotonin norepinephrine reuptake inhibitors (SNRIs) such as venlafaxine, duloxetine?
- Have you ever experienced numbness on one side of your body when you have a headache?
- Have you ever had, or do you have epilepsy or seizures?
- Have you ever had, or do you have liver or kidney problems?
- Is this headache different from your usual migraine attacks?
- Are you over 65 years of age?
- Have you taken or will you be taking any of the following medicines within 72 hours: ketoconazole, itraconazole, nefazodone, troleandomycin, clarithromycin, ritonavir, and nelfinavir? These medicines may cause an increase in the amount of RELPAX in the blood increasing the risk of serious side effects.

If you answered **yes** to any of the above questions, discuss them all with your physician before taking RELPAX.

INTERACTIONS WITH THIS MEDICATION

Some medicines may increase the risk of serious side effects if taken concurrently with RELPAX.

Do not take RELPAX if you
- have taken any of the following medicines in the last 72 hours: ketoconazole, itraconazole, nefazodone, troleandomycin, clarithromycin, ritonavir, and nelfinavir?
- have taken the following medicines in the last 24 hours: other "triptans" like almotriptan, sumatriptan, naratriptan, zolmitriptan, rizatriptan or ergotamine-type medications such as ergotamine, dihydroergotamine or methysergide.

Ask your physician for instructions about taking RELPAX if you are taking selective serotonin reuptake inhibitors (SSRIs) such as sertraline, escitalopram and fluoxetine or serotonin norepinephrine reuptake inhibitors (SNRIs) such as venlafaxine, duloxetine for depression. A life-threatening condition called serotonin syndrome can happen when medicines called triptans, such as RELPAX, and medicines used to treat depression and mood disorders called SSRIs or SNRIs are used together. Signs and symptoms of serotonin syndrome include the following: restlessness, diarrhea, hallucinations, coma, loss of coordination, nausea, fast heart beat, vomiting, increased body temperature, changes in blood pressure and overactive reflexes.

PROPER USE OF THIS MEDICATION

Usual dose:
For adults, the dosage is 20 or 40 mg, as recommended by your physician. The dose should be taken as soon as your migraine appears, but it may be taken at any time during your migraine headache.

RELPAX tablets should be swallowed whole with water.

If your first dose is 20 mg, a second dose of 20 mg may be taken if your headache returns. Repeat doses cannot be taken any sooner than 2 hours following the first dose. Do not take more than 40 mg in any 24-hour period.

If the first dose does not relieve the symptoms, do not take further doses for the same attack.

A reminder: This medicine has been prescribed only for you. Only a doctor knows who can use it safely. Never give this medication to anyone else. It may harm them, even if their symptoms are the same as yours.

Overdose:
If you have taken more medication than your physician has instructed, contact either your physician, hospital emergency department, or nearest poison control centre immediately.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side Effects to Watch for: Although the vast majority of RELPAX users have not experienced any significant problems, you should be aware of the following side effects:

- **Sensations of pain, pressure or tightness in the chest, neck, throat, jaw or arms. If this happens to you, then discuss it with your doctor before using any more RELPAX. If the chest pain is severe (may resemble an angina attack) or does not go away, call your doctor immediately.**
- **Shortness of breath; wheezing; heart throbbing; swelling of face, lips, eyelids; skin rash; skin lumps; or hives. Tell your doctor immediately. Do not continue to take RELPAX unless advised by your doctor.**
- Feeling weak, dizziness, feeling sleepy or drowsy, tingling, difficulty swallowing, nausea and stomach pain/cramps.
- Drowsiness in some patients. Dizziness and drowsiness have also been reported in some patients receiving RELPAX. Therefore, do not drive or operate machinery if you are experiencing these symptoms or side effects.

If you feel unwell in any other way or have any symptoms that you do not understand, contact your doctor or pharmacist.

This is not a complete list of side effects. For any unexpected effects while taking RELPAX, contact your doctor or pharmacist.

HOW TO STORE IT

Keep your medicine in a safe place where children cannot reach it. RELPAX could be harmful to children. Store your medication between 15 and 30ºC, away from direct heat, light, and moisture.

If your doctor tells you to stop taking RELPAX or if your medicine has expired, discard it by returning it to your pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789, or**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 0701E
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
http://www.viatris.ca
or by contacting the sponsor, BGP Pharma ULC, at:
1-844-596-9526.
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