

**PART III: CONSUMER INFORMATION****Pr ELETRIPTAN  
(eletriptan hydrobromide)**

**This leaflet is part III of a three-part “Product Monograph” published when ELETRIPTAN was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ELETRIPTAN. 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 ELETRIPTAN. This medicine is one of a group of antimigraine drugs called 5-HT<sub>1</sub> agonists.

ELETRIPTAN 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. ELETRIPTAN narrows the vessels and relieves the pain and other symptoms of migraine headache

**When it should not be used:**

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

Do not take ELETRIPTAN 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 ELETRIPTAN 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 ELETRIPTAN and taking them together increases the risk of serious side effects.

Do not use ELETRIPTAN 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: colloidal silicon dioxide, croscarmellose sodium, FD & C Yellow No 6, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, titanium dioxide and triacetin.

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

**What dosage forms it comes in:**

ELETRIPTAN tablets for oral administration are

**20 mg:** Orange, round biconvex film-coated tablet, engraved with **8310** on one side and **93** on the other side

**40 mg:** Orange, round, biconvex film-coated tablet, engraved with **8311** on one side and **93** on the other side and contain 20 or 40 mg of eletriptan base.

**WARNINGS AND PRECAUTIONS**

The decision to use ELETRIPTAN 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 ELETRIPTAN is appropriate for you.

**Important Questions to Consider Before Taking**

**ELETRIPTAN:** 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 ELETRIPTAN.

- 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<sub>1</sub> 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 disease or kidney Disease?
- 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 eletriptan hydrobromide 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 ELETRIPTAN.

## INTERACTIONS WITH THIS MEDICATION

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

Do not take ELETRIPTAN 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 ELETRIPTAN 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 ELETRIPTAN, 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.

ELETRIPTAN 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 eletriptan hydrobromide 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 ELETRIPTAN. 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 ELETRIPTAN 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 eletriptan hydrobromide. 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 ELETRIPTAN, contact your doctor or pharmacist.*

## HOW TO STORE IT

Keep your medicine in a safe place where children cannot reach it. ELETRIPTAN could be harmful to children. Store your medication between 15°C and 30°C.

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

## Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. 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 by Pro Doc Ltée at 1-800-361-8559, [www.prodqc.ca](http://www.prodqc.ca) or [info@prodqc.ca](mailto:info@prodqc.ca).

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