

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

#### **Pr MYLAN-SUMATRIPTAN**

##### **Sumatriptan Tablets**

Read this carefully before you start taking **MYLAN-SUMATRIPTAN** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **MYLAN-SUMATRIPTAN**.

##### **What is MYLAN-SUMATRIPTAN used for?**

MYLAN-SUMATRIPTAN is used in adults to relieve migraine headaches. These migraine headaches may or may not be accompanied by an aura. This is when you may see black spots, flashes of light or shimmering spots or stars. MYLAN-SUMATRIPTAN should not be used to prevent or reduce the number of headaches you experience. Use MYLAN-SUMATRIPTAN only to treat an actual migraine headache attack.

##### **How does MYLAN-SUMATRIPTAN work?**

Migraine headache is believed to be caused by a widening of the blood vessels in the head. MYLAN-SUMATRIPTAN narrows these vessels and relieves the symptoms of migraine headache.

##### **What are the ingredients in MYLAN-SUMATRIPTAN?**

Medicinal ingredients: Sumatriptan succinate.

Non-medicinal ingredients: Croscarmellose sodium, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, synthetic red iron oxide (100 mg only), synthetic yellow iron oxide (100 mg only), titanium dioxide and triacetin.

##### **MYLAN-SUMATRIPTAN comes in the following dosage forms:**

**25 mg:** White to off-white, round film-coated tablets debossed "G" on one side and "SU25" on the other side. Blister packs containing 6 tablets.

**50 mg:** White to off-white, triangular-shaped film-coated tablets debossed "G" on one side and "SU50" on the other side. Blister packs containing 6 tablets.

**100 mg:** Pink, triangular-shaped film-coated tablets debossed "G" on one side and "SU100" on the other side. Blister packs containing 6 tablets.

**Do not use MYLAN-SUMATRIPTAN if:**

- you are allergic to sumatriptan or to any of the ingredients in MYLAN-SUMATRIPTAN (See “What are the ingredients in MYLAN-SUMATRIPTAN?”).
- you have a heart problem such as heart failure or chest pains (angina), or have already had a heart attack.
- you have had a stroke or a mini-stroke (also called a transient ischaemic attack or TIA).
- you have a history, symptoms or signs of peripheral vascular disease. This is a reduced blood flow to the limbs and organs other than the heart and brain, such as ischemic bowel disease and Raynaud’s syndrome.
- you have uncontrolled or severe high blood pressure.
- you are taking or have taken within the past 2 weeks, a monoamine oxidase inhibitor (MAO), medication (such as phenelzine sulfate, tranylcypromine sulfate, moclobemide or selegiline).
- you are taking or have taken within the past 24 hours, medication containing ergotamine, dihydroergotamine, methysergide, or another triptan used to treat migraine headaches. If you are not sure if you have been prescribed these types of medications, ask your healthcare professional.
- you have severe liver problems.
- you have certain other types of migraine headaches including:
  - hemiplegic migraines. These are migraine headaches where you have weakness on one side of your body, or
  - basilar migraines. These are migraine headaches that start in the lower part of the brain, or
  - ophthalmoplegic migraines. These are migraine headaches where you have pain around the eyes.

If you are not sure if you have these types of migraines, ask your healthcare professional.

MYLAN-SUMATRIPTAN Tablets should not be used for the treatment of other types of headaches that are different from migraine attacks.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MYLAN-SUMATRIPTAN. Talk about any health conditions or problems you may have, including if you:**

- are pregnant, think you might be pregnant, or are trying to become pregnant.
- are breastfeeding. The active ingredient in MYLAN-SUMATRIPTAN, sumatriptan, will pass into your breast milk. Avoid breastfeeding for 24 hours after taking MYLAN-SUMATRIPTAN.
- you have risk factors for heart disease. This includes high blood pressure, high cholesterol, obesity, diabetes, smoking, strong family history of heart disease, or you are postmenopausal or a male over 40.
- have ever had to stop taking this or any other medication because of an allergy or other problems, or you are allergic to drugs containing sulphonamides.
- are under 18 years of age.
- are over 65 years of age.
- had or have any liver or kidney problems.
- had or have epilepsy or seizures.
- experience a headache that is different from your usual migraine attacks.

**Other warnings you should know about:**

**Taking MYLAN-SUMATRIPTAN can cause serious side effects, including:**

- Serious heart problems
- Long term eye problems
- Raynaud's Syndrome

See the **Serious side effects and what to do about them** table, below for more information on these and other serious side effects.

**Serotonin toxicity (also known as Serotonin syndrome):** MYLAN-SUMATRIPTAN can cause serotonin toxicity, a rare but potentially life-threatening condition. It can cause serious changes in how your brain, muscles and digestive system work. You may develop serotonin toxicity if you take MYLAN-SUMATRIPTAN with certain medication to treat depression.

Serotonin toxicity symptoms include:

- fever, sweating, shivering, diarrhea, nausea, vomiting;
- muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination;
- fast heartbeat, changes in blood pressure;
- confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, and coma.

**Continuous use of MYLAN-SUMATRIPTAN:** MYLAN-SUMATRIPTAN should not be used continuously to prevent or reduce the number of attacks you experience. Use MYLAN-SUMATRIPTAN only to treat an actual migraine headache attack. If you use MYLAN-SUMATRIPTAN too often, it may make your migraine headaches worse. If this happens, your healthcare professional may tell you to stop taking MYLAN-SUMATRIPTAN.

**Driving and Operating Machines:** MYLAN-SUMATRIPTAN can cause dizziness which may affect your ability to drive or use machines. Wait to see how you respond to MYLAN-SUMATRIPTAN before you drive or use machines.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with MYLAN-SUMATRIPTAN:**

- Medicines used to treat depression such as MAO Inhibitors, selective serotonin reuptake inhibitors (SSRIs), and serotonin noradrenaline reuptake inhibitors (SNRIs).
- Other medicines used to treat migraine headaches such as triptans, 5-HT<sub>1</sub> agonists, ergotamine, dihydroergotamine, and methysergide.

**How to take MYLAN-SUMATRIPTAN:**

- Take MYLAN-SUMATRIPTAN with water and swallow the tablet **whole**. MYLAN-SUMATRIPTAN should not be chewed, divided or crushed.
- MYLAN-SUMATRIPTAN can be taken at any time during your migraine headache.
- It may take up to 30 minutes for MYLAN-SUMATRIPTAN to start working.

- If after taking MYLAN-SUMATRIPTAN you need more pain relief, you can take another pain medication. This medication should not contain ergotamine. If you are not sure which medications you can use talk to your healthcare professional.
- For subsequent migraine headaches, you may take MYLAN-SUMATRIPTAN.

**Remember, this medicine has been prescribed only for you. Do not give it to anybody else, as they may experience undesirable effects, which may be serious.**

**Usual dose:**

- The usual adult dose is 50 mg.
- Based on your response and tolerability, your healthcare professional may increase your dose to 100 mg. The maximum dose is 100 mg.
- If you do not respond to the first dose of MYLAN-SUMATRIPTAN, do not take a second dose for the same attack.
- If your symptoms come back, and it has been two or more hours since your first tablet, you may take a second tablet.
- DO NOT take more than 200 mg in any 24-hour period.

**Overdose:**

If you think you, or a person you are caring for, have taken too much MYLAN-SUMATRIPTAN, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**What are possible side effects from using MYLAN-SUMATRIPTAN?**

These are not all the possible side effects you may feel when taking MYLAN-SUMATRIPTAN. If you experience any side effects not listed here, contact your healthcare professional.

The most commonly reported side effects of MYLAN-SUMATRIPTAN are:

- flushing (redness of the face lasting for a short time)
- feeling sick or vomiting
- dizziness
- drowsiness
- tiredness
- weakness
- temporary increase in blood pressure
- aching muscles

Other side effects include:

- trouble with eyesight, such as blind spots, flashes of light, and seeing two images of a single object
- shaking, tremors or uncontrolled movements
- loss of normal colour in the fingers and toes
- diarrhea
- sweating

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>COMMON</b>			
Unusual sensations or discomfort including numbness, tingling, feeling hot or cold; pain, heaviness or pressure in any part of the body including chest, throat, neck, jaw and upper limbs.	✓		
<b>VERY RARE</b>			
<b>Symptoms of a heart attack:</b> chest pain, sweating, shortness of breath.			✓
<b>Heart rhythm problems:</b> unusually slow or fast heartbeats, or a feeling of irregular and/or forceful heartbeats.	✓		
<b>Allergic reactions:</b> shortness of breath, sudden wheeziness, chest tightness, swelling of the eyelids, face or lips, lumpy skin rash or hives.			✓
<b>Seizures:</b> loss of consciousness with uncontrollable shaking (“fit”).			✓
Lower abdominal pain and/or severe rectal bleeding.			✓
<b>Raynaud’s syndrome:</b> persistent purple discolouration of hands or feet.			✓
Loss of vision.			✓
<b>UNKNOWN</b>			
<b>Serotonin toxicity:</b> a reaction which may cause feelings of agitation or restlessness, flushing, muscle twitching, involuntary eye movements, heavy sweating, high body temperature (>38°C), or rigid muscles.			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

### 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.*

### Storage:

Keep your tablets in a cool, dry place (15°C to 30°C).

Medicines should not be disposed of via wastewater or household waste. Your healthcare professional will throw away any medicines that are no longer being used. These measures will help protect the environment.

Keep out of reach and sight of children.

### If you want more information about MYLAN-SUMATRIPTAN:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website [www.mylan.ca](http://www.mylan.ca), or by calling 1-844-596-9526.

This leaflet was prepared by Mylan Pharmaceuticals ULC.

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