

PART III: CONSUMER INFORMATION

**PrSandoz Almotriptan
(Almotriptan tablets)**

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

ABOUT THIS MEDICATION**What the medication is used for:**

Sandoz Almotriptan (almotriptan malate) tablet is a medication used for acute treatment of migraines with or without aura in adults and adolescents aged 12 – 17 years. **Sandoz Almotriptan is not for use in children under 12 years of age.** Sandoz Almotriptan should not be used continuously to prevent or reduce the number of attacks you experience. Sandoz Almotriptan is a member of a class of drugs called selective 5-HT_{1B/1D} receptor agonists.

Tell your doctor about your symptoms. Your doctor will decide if you have migraines. Use Sandoz Almotriptan only for a migraine attack. Sandoz Almotriptan should not be used to treat headaches that might be caused by other, more serious conditions.

You will find more information about migraine at the end of this leaflet.

What is migraine and how does it differ from other headaches?

Migraine is an intense, throbbing, typically one-sided headache that often includes nausea, vomiting, sensitivity to light, and sensitivity to sound. According to many migraine sufferers, the pain and symptoms from a migraine headache are more intense than the pain and symptoms of a common headache.

Some people may have visual symptoms before the headache, such as flashing lights or wavy lines, called an aura.

Migraine attacks typically last for hours or, rarely, for more than a day, and they can return frequently. The severity and frequency of migraine attacks may vary.

Based on your symptoms, your doctor will decide whether you have a migraine.

Who gets migraines?

Migraine headaches tend to occur in members of the same family. Both men and women get migraine, but it is more common in women.

What may trigger a migraine attack?

Certain things are thought to trigger migraine attacks in some people. Some of these triggers are:

- Certain foods or beverages (e.g. cheese, chocolate, citrus fruit, caffeine, alcohol)
- Stress
- Change in behaviour (e.g. under/oversleeping; missing a

meal; change in diet)

- Hormonal changes in women (e.g. menstruation)

You may be able to prevent migraine attacks or diminish their frequency if you understand what specifically triggers your attacks. Keeping a headache diary may help you identify and monitor the possible migraine triggers you encounter. Once the triggers are identified, you and your doctor can modify your treatment and lifestyle appropriately.

What it does:

Migraine headache is believed to be caused by a widening of the blood vessels in the head. Sandoz Almotriptan narrows the vessels and relieves the pain and other symptoms of migraine headache.

When it should not be used:

Do not take Sandoz Almotriptan if you have:

- had a serious allergic reaction to Sandoz Almotriptan or any of its ingredients;
- uncontrolled high blood pressure;
- heart disease or history of heart disease.
- severe liver disease

Sandoz Almotriptan should not be used within 24 hours of treatment with another 5-HT_{1B/1D} agonist, such as naratriptan (Amerge[®]), rizatriptan (Maxalt[®]), sumatriptan (Imitrex[®]), or zolmitriptan (Zomig[®]); or ergotamine type medications such as ergotamine (Bellergal[®] Spacetabs[®], Cafergot[®], Ergodryl[™]), dihydroergotamine (Dihydroergotamine (DHE), Migranal[®]), or methysergide (Sansert[®]). (The brands listed are the trademarks of their respective owners and are not trademarks of Sandoz Canada Inc.)

What the medicinal ingredient is:

Almotriptan (as almotriptan malate)

What the important nonmedicinal ingredients are:

hypromellose, mannitol, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, sodium stearyl fumarate, and titanium oxide.

What dosage forms it comes in:

Tablets: 12.5 mg

WARNINGS AND PRECAUTIONS

BEFORE you use Sandoz Almotriptan talk to your doctor or pharmacist if you:

- Have past or present medical problems
- Have a history of high blood pressure, chest pain, shortness of breath, strokes, or heart disease
- Have risk factors for heart disease, such as:
 - High blood pressure or diabetes
 - High cholesterol
 - Obesity
 - Smoking
 - Family history of heart disease
 - You are a post-menopausal woman

- You are a male over 40 years of age
- Have or have had allergies
- Have or have had allergic reactions to sulfonamides, also known as sulfa drugs (ask your doctor if you are not sure what sulfonamide drugs are)
- Have kidney or liver disease
- Plan to become or are already pregnant
- Plan to breastfeed, or if you are already breastfeeding an infant
- Plan to take or are taking drugs, including those obtained without a prescription, and those you normally take for a migraine.

Do not use Sandoz Almotriptan if you are pregnant, think you might be pregnant, are trying to become pregnant, or are not using adequate contraception, unless you have discussed this with your doctor.

If you use Sandoz Almotriptan too often, it may make your headaches worse. If this happens, your doctor may tell you to stop taking Sandoz Almotriptan.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with Sandoz Almotriptan include:

- Other drugs in the same class
- Ergotamine-type medications
- Monoamine oxidase inhibitors (MAOIs)
- Ketoconazole, itraconazole, ritonavir or erythromycin
- Selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs)
- Herbal products that contain St. John's Wort (*Hypericum perforatum*)

Do not take Sandoz Almotriptan with any other drug in the same class within 24 hours, such as naratriptan (Amerge[®]), rizatriptan (Maxalt[®]), sumatriptan (Imitrex[®]), or zolmitriptan (Zomig[®]).

Do not take Sandoz Almotriptan within 24 hours of taking ergotamine-type medications such as ergotamine (Bellergal[®] Spacetabs[®], Cafergot[®], Ergodryl[™]), dihydroergotamine (Dihydroergotamine (DHE), Migranal[®]), or methysergide (Sansert[®]) to treat your migraine.

Tell your doctor if you are taking monoamine oxidase (MAO) inhibitors, such as phenelzine sulfate (Nardil[™]), moclobemide (Manerix[®]) or tranylcypromine sulfate (Parnate[®]) for mental depression, or if it has been less than two weeks since you stopped taking a MAO inhibitor.

Tell your doctor if you are taking ketoconazole (Nizoral[®], Apo[®]-Ketoconazole, Novo-Ketoconazole), itraconazole (SPORANOX[®]), ritonavir (Norvir[®]), or erythromycin (Apo[®]-Erythro, Diomycin[®], Erybid[™], Eryc[®], Erythrocin[®], Erythromid[®], Novo-Rythro Encap, PCE[®], PMS-Erythromycin), or if it has been less than one week since you stopped taking one of these drugs.

Ask your doctor for instructions about taking Sandoz Almotriptan if you are taking selective serotonin reuptake inhibitors (SSRIs)

such as sertraline, escitalopram and fluoxetine or serotonin norepinephrine reuptake inhibitors (SNRIs) such as venlafaxine or duloxetine for depression. A life-threatening condition called serotonin syndrome can happen when medicines called triptans, such as Sandoz Almotriptan, 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 heartbeat, vomiting, increased body temperature, changes in blood pressure and overactive reflexes.

PROPER USE OF THIS MEDICATION

Usual dose:

Your doctor has prescribed a 12.5 mg dose of Sandoz Almotriptan for your migraine attack. When you have a migraine headache, take your medication as directed by your doctor. If your headache comes back after your initial dose, you may take a second dose any time **after 2 hours** of administering the first dose. If you had no pain relief after the first dose, do **not** take a second dose without first consulting with your doctor. Do not take more than 25 mg of Sandoz Almotriptan in a 24-hour period (for example, do not take more than two 12.5 mg tablets in 24 hours). If your condition worsens, seek medical attention.

Overdose:

If you take more medication than you have been told to take, you should contact your doctor, hospital emergency department, or nearest poison control centre immediately, even if you do not feel sick.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all prescription drugs, Sandoz Almotriptan can cause side effects. In studies, Sandoz Almotriptan was generally well tolerated. The side effects were usually mild and temporary. The following is **not** a complete list of side effects reported with Sandoz Almotriptan. Do not rely on this leaflet alone for information about side effects. Ask your doctor to discuss with you the more complete list of side effects.

In studies, the **most common** side effects reported were:

- Nausea
- Sleepiness
- Dizziness
- Tingling sensation
- Headache
- Dry mouth

Other side effects that may rarely occur include: shortness of breath, wheeziness, heart throbbing, increased blood pressure, fast heart rate or irregular heart rate.

If any of these occur, do not take any more Sandoz Almotriptan

and contact your doctor immediately.

If you experience sleepiness after taking Sandoz Almotriptan, you should not perform complex tasks such as driving or operating heavy machinery until you are sure you are no longer sleepy or drowsy.

Call your doctor immediately if you feel tightness, pain, pressure or heaviness in your chest, throat, neck or jaw after taking Sandoz Almotriptan. Do not take Sandoz Almotriptan again until your doctor has checked you.

Call your doctor immediately if you feel unwell or have any other symptoms that you do not understand or find distressing while taking Sandoz Almotriptan.

Call your doctor immediately if you experience any symptoms that suggest an allergic reaction (such as a rash or itching) after taking Sandoz Almotriptan.

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

do so. Throw away your medicine as instructed. Be sure that discarded tablets are out of the reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](#);
 - By calling 1-866-234-2345 (toll-free);
 - By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 0701E
Ottawa, ON
K1A 0K9
- Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

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 contacting the sponsor, Sandoz Canada Inc., at:

1-800-361-3062

or by written request at:
145 Jules-Léger
Boucherville QC
J4B 7K8

Or by e-mail at:
medinfo@sandoz.com

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SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug, call and seek urgent medical attention
		Only if severe	In all cases	
Rare	Shortness of breath, wheeziness, heart throbbing, increased blood pressure, fast heart rate or irregular heart rate.			✓
Very rare	Tightness, pain, pressure or heaviness in your chest, throat, neck or jaw.			✓
Very rare	Allergic reaction (swelling of the eyelids, face, or lips; skin rash, itchy rash, skin lumps or hives).			✓

HOW TO STORE IT

Keep your medicine in a safe place where children cannot reach it. It could be harmful to children. Store your medication at room temperature (15°C to 30°C). If your medication has expired, throw it away as instructed. If your doctor decides to stop your treatment, do not keep any leftover medicine unless your doctor tells you to