

PART III: CONSUMER INFORMATION**Pr RIZATRIPTAN ODT**

Rizatriptan Orally Disintegrating Tablets
5 mg and 10 mg rizatriptan (as rizatriptan benzoate)

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

Please read this leaflet carefully before you take RIZATRIPTAN ODT. It provides a summary of the information available on your medication. Please do not throw it away. Keep it for reference until you have finished your medicine. This leaflet does not contain all the information available on RIZATRIPTAN ODT. For further information or advice, ask your physician or pharmacist.

ABOUT THIS MEDICATION

The name of your medicine is RIZATRIPTAN ODT. It can only be obtained by prescription from your physician. The decision to use RIZATRIPTAN ODT is one that you and your physician 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), tell your physician. Your physician should evaluate you for heart disease in order to determine whether RIZATRIPTAN ODT is appropriate for you.

What the medication is used for:

RIZATRIPTAN ODT is intended to relieve your migraine headache and other associated symptoms of a migraine attack in adults. **RIZATRIPTAN ODT should not be used continuously to prevent or reduce the number of attacks you experience. Use RIZATRIPTAN ODT only to treat an actual migraine headache attack.**

What it does:

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

When it should not be used:

Do not take RIZATRIPTAN ODT if you:

- are allergic to any of the ingredients (see **What the nonmedicinal ingredients are section**)
- have uncontrolled or severe high blood pressure
- have heart disease or history of heart disease
- have severe liver disease

- have had a stroke or transient ischemic attack (TIA) have or have had blood vessels problems, including ischemic bowel disease
- take monoamine oxidase (MAO) inhibitors such as moclobemide, phenelzine, tranylcypromine, or pargyline, or have taken MAO inhibitors within the last two weeks.

RIZATRIPTAN ODT should not be used to relieve pain other than that associated with migraine headache.

RIZATRIPTAN ODT should not be used within 24 hours of treatment with another 5-HT₁ agonist such as sumatriptan, naratriptan or zolmitriptan, or ergotamine-type medications such as ergotamine, dihydroergotamine or methysergide.

Please also see WARNINGS AND PRECAUTIONS.

What the medicinal ingredient is:

Rizatriptan benzoate

What the nonmedicinal ingredients are:

Aspartame, calcium silicate, crospovidone, silicified microcrystalline cellulose, sweet orange flavour, magnesium stearate, mannitol, colloidal silicon dioxide.

What dosage forms it comes in:

RIZATRIPTAN ODT is available as white to grey-white round orally disintegrating tablets containing 5 or 10 mg rizatriptan as rizatriptan benzoate.

WARNINGS AND PRECAUTIONS

If the answer to any of the following questions is YES or if you do not know the answer, then please speak with your physician before you take any RIZATRIPTAN ODT.

- 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 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 ever had a heart attack or stroke?
- **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-HT₁ agonist medications such as sumatriptan succinate/sumatriptan or naratriptan (as naratriptan hydrochloride), zolmitriptan or migraine medications containing ergotamine, dihydroergotamine, or methysergide?
- Are you taking any medications for depression such as selective serotonin reuptake inhibitors (SSRIs) like sertraline, escitalopram oxalate, and fluoxetine or serotonin norepinephrine reuptake inhibitors (SNRIs) such as venlafaxine, duloxetine, or monoamine oxidase inhibitors (MOIs)?
- 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?

Phenylketonuric patients:

You should be aware that this product contains phenylalanine (a component of aspartame). Each 5 mg RIZATRIPTAN ODT contains 1.57 mg phenylalanine and each 10 mg RIZATRIPTAN ODT contains 3.14 mg phenylalanine.

Continuous use of RIZATRIPTAN ODT:

If you take RIZATRIPTAN ODT too often, this may result in you getting chronic headaches or marked increases in the frequency of your migraine attacks. In such cases, you should contact your doctor, as you may have to stop taking RIZATRIPTAN ODT

If you are not sure whether you should take RIZATRIPTAN ODT contact your physician or pharmacist.

RIZATRIPTAN ODT use during pregnancy:

Do not use RIZATRIPTAN ODT 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.

INTERACTIONS WITH THIS MEDICATION

If you are taking any other migraine medication, check with your physician first before taking RIZATRIPTAN ODT and inform your physician of any other medications you may be taking, including those obtained without a prescription.

Do not take RIZATRIPTAN ODT if you take monoamine oxidase (MAO) inhibitors such as moclobemide, phenelzine, tranylcypromine, or pargyline, or have taken MAO inhibitors within the last two weeks.

Ask your physician for instructions about taking RIZATRIPTAN ODT if you are taking selective serotonin reuptake inhibitors (SSRIs) such as sertraline, escitalopram oxalate, 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 RIZATRIPTAN ODT and medicines used to treat depression and mood disorders called SSRIs and 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

REMEMBER: this medicine was prescribed only for **YOU**. Only a physician knows who can use it safely. Never give it to someone else. It may harm them, even if their symptoms are the same as yours.

Usual dose

For adults, the usual dosage is 5 or 10 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.

If you are using RIZATRIPTAN ODT leave the tablet in its package until you are ready to take it. Do not push the tablet through the blister; rather, peel open the blister pack with dry hands and place the tablet on your tongue. The tablet will dissolve rapidly and be swallowed with your saliva. No liquid is needed to take the RIZATRIPTAN ODT tablet.

A second dose 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 20 mg in any 24-hour period.

For any attack where you have no response to the first dose, do not take a second dose without first consulting your physician.

Overdose:

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

Although the vast majority of rizatriptan benzoate users have not experienced any significant problems, you should be aware of the following side effects:

Common 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 physician before using any more RIZATRIPTAN ODT. If the chest pain is severe (may resemble an angina attack) or does not go away, stop taking drug and call your physician immediately.
- Tingling, heat, heaviness or pressure, dizziness, tiredness, or feeling sick. Tell your physician if you have any of these symptoms.
- Drowsiness. Do not drive or operate machinery until you are sure that you are not drowsy.
- Irregular or rapid heartbeats. If this happens to you, stop taking drug and then discuss it with your physician before using any more RIZATRIPTAN ODT.

Uncommon side effects

- Rapid onset of numbness or weakness on one side of the body (often beginning in one arm). If this occurs, stop taking drug and call your physician immediately.
- Muscle pain. If this occurs, stop taking drug and call your physician immediately.

Rare side effects

- Shortness of breath, wheeziness, heart throbbing, swelling of the eyelids, face, tongue or lips; or a skin rash or skin lumps or hives or spasms of blood vessels of the extremities including coldness and numbness of the hands and feet. These effects happen rarely, but if any do occur, do not take any more RIZATRIPTAN ODT and contact your physician immediately.
- Sudden or severe abdominal pain. If this occurs, stop taking drug and call your physician immediately.

Very rare side effects

- There have been very rare reports of seizures. If this occurs, stop taking drug and call your physician immediately.
- Spasm of the blood vessels of the colon (large bowel). If this occurs, stop taking drug and call your physician immediately.

If you feel unwell in any other way or have symptoms that you do not understand or find distressing, you should contact your physician immediately.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom/effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
	the chest, neck, throat, jaw or arms			
	Tingling, heat, heaviness or pressure in any part of the body	✓		
	Headache, dizziness, tiredness, nausea, vomiting, dry mouth, drowsiness	✓		
	Irregular or rapid heartbeats			✓
Uncommon	Rapid onset of numbness or weakness on one side of the body (often beginning in one arm)			✓
	Muscle pain			✓
Rare	Shortness of breath, wheeziness, heart throbbing, swelling of the eyelids, face, tongue or lips; or a skin rash or skin lumps or hives or spasm of blood vessels of the extremities			✓
	Sudden or severe abdominal pain			✓
Very Rare	Seizure			✓
	Spasm of the blood vessels of the colon (large bowel)			✓

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

HOW TO STORE IT

Keep your medicine in a safe place where children cannot reach it. RIZATRIPTAN ODT could be harmful to children. Store your medication between 15 and 30°C in the original blister, away from direct heat.

RIZATRIPTAN ODT should not be removed from the blister until you are ready to take the tablet.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom/effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Sensations of pain, pressure or tightness in			✓

If your physician decides to stop your treatment, do not keep any leftover medicine unless your physician tells you to do so.

If your medicine has expired, do not use it. It is recommended to take leftover medication to a pharmacy for proper disposal.

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, ON 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 by contacting the sponsor, Sivem Pharmaceuticals ULC at, 1-855-788-3153

Or at www.sivem.ca

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