

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

Pr ZOMIG® and Pr ZOMIG RAPIMELT® zolmitriptan

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

REMEMBER: this medicine was prescribed only for YOU. Only a doctor 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.

ABOUT THIS MEDICATION

The name of your medicine is ZOMIG or ZOMIG RAPIMELT which can only be obtained by prescription from your doctor. The decision to use ZOMIG/ZOMIG RAPIMELT 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 post-menopausal female, or a male over 40), tell your doctor. Your doctor should evaluate you for heart disease in order to determine if ZOMIG/ZOMIG RAPIMELT are appropriate for you.

WHAT THE MEDICATION IS USED FOR:

ZOMIG and ZOMIG RAPIMELT belong to a group of anti-migraine drugs called 5-HT₁ agonists. ZOMIG/ZOMIG RAPIMELT is used to relieve your migraine headache and other associated symptoms of a migraine attack.

ZOMIG/ZOMIG RAPIMELT should not be used continuously to prevent or reduce the number of attacks you experience. Use ZOMIG/ZOMIG RAPIMELT 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. ZOMIG/ZOMIG RAPIMELT narrows the vessels and relieves the pain and other symptoms of migraine headache.

WHEN IT SHOULD NOT BE USED:

ZOMIG/ZOMIG RAPIMELT should not be used if:

- you are allergic to zolmitriptan or any of the other ingredients in ZOMIG/ZOMIG RAPIMELT (see “WHAT THE NONMEDICINAL INGREDIENTS ARE”)

- you have a history, or any symptoms or signs of a heart condition
- you suffer from chest pain, occurring either on exertion or at rest (the latter condition is known as Prinzmetal’s Angina)
- you have severe or uncontrolled hypertension
- you are taking or have recently taken (within 24 hours) an ergotamine containing or ergot-like drug, or another triptan used to treat migraines
- you have another type of headache that is different from a migraine attack
- you are taking or have recently taken (within 2 weeks) a monoamine oxidase inhibitor (MAOI)

WHAT THE MEDICINAL INGREDIENT IS:

Both ZOMIG and ZOMIG RAPIMELT tablets contain 2.5 mg of zolmitriptan as the active ingredient.

WHAT THE IMPORTANT NONMEDICINAL INGREDIENTS ARE:

ZOMIG contains: anhydrous lactose, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, hydroxypropyl methylcellulose, titanium dioxide, polyethylene glycol, and yellow iron oxide.

ZOMIG RAPIMELT contains: aspartame, citric acid, colloidal silicon dioxide, crospovidone, magnesium stearate, mannitol, microcrystalline cellulose, orange flavour, and sodium bicarbonate. Each 2.5 mg ZOMIG RAPIMELT contains 2.81mg of phenylalanine.

WHAT DOSAGE FORMS IT COMES IN:

ZOMIG is supplied in conventional tablets of 2.5 mg in blister packs containing 6 tablets.

ZOMIG RAPIMELT is supplied in orally dispersible tablets of 2.5 mg in blister packs containing 6 tablets.

WARNINGS AND PRECAUTIONS

BEFORE you use ZOMIG/ZOMIG RAPIMELT talk to your doctor or pharmacist if the answer to any of the following questions is YES, or if you do not know the answer:

- Are you pregnant, think you might be pregnant, or trying to become pregnant? Are you using inadequate contraception? Are you breastfeeding?
- 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, or irregular heart beats (including a fast heart beat called Wolff-Parkinson-White syndrome)? Do you have angina? Have you ever had heart or blood vessel disease? Do you have a history of cerebral bleeding? Have you 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?
- Do you have a condition called phenylketonuria (a specific blood disorder)?
- Do you have rare hereditary problems of galactose intolerance?

- Are you post-menopausal or a male over 40?
- Do you have high blood pressure?
- 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, naratriptan hydrochloride, rizatriptan benzoate, almotriptan malate or migraine medications containing ergotamine, dihydroergotamine, or methysergide?
- Are you taking any medications for depression such as selective serotonin reuptake inhibitors (SSRI's), for example, fluoxetine hydrochloride, sertraline hydrochloride, fluvoxamine maleate, paroxetine hydrochloride, etc., or serotonin norepinephrine reuptake inhibitors (SNRIs), for example, venlafaxine hydrochloride, or monoamine oxidase inhibitors (MAOIs), for example, phenelzine sulfate, tranylcypromine sulfate or moclobemide?
- Have you ever experienced numbness on one side of your body when you have a headache?
- Have you ever had epilepsy or seizures?
- Have you ever had liver disease?
- Are you over 65 years of age?
- Is this headache different from your usual migraine attacks?
- Are you taking cimetidine (for treatment of indigestion or stomach ulcers) or a member of the quinolone family of antibiotics (for example ciprofloxacin)?

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

ZOMIG tablets contain lactose which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest milk or some sugars, talk to your doctor before taking this medicine.

Use of ZOMIG/ZOMIG RAPIMELT during pregnancy:
Do not use ZOMIG or ZOMIG RAPIMELT 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 doctor.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist about any other drugs you take, including:

- other 5-HT₁ agonist migraine drugs (sumatriptan succinate, naratriptan hydrochloride, rizatriptan benzoate, almotriptan malate) or migraine drugs that contain ergotamine, dihydroergotamine, methysergide
- drugs for depression such as selective serotonin reuptake inhibitors (SSRI's), for example, fluoxetine hydrochloride, sertraline hydrochloride, fluvoxamine maleate, paroxetine hydrochloride, etc., or serotonin norepinephrine reuptake inhibitors (SNRIs), for example, venlafaxine hydrochloride, or monoamine

oxidase inhibitors (MAOIs), for example, phenelzine sulfate, tranylcypromine sulfate or moclobemide

- drugs used to treat upset stomach or stomach ulcers (cimetidine)
- antibiotics from the quinolone family (for example ciprofloxacin)

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those that can be bought without a prescription.

PROPER USE OF THIS MEDICATION

USUAL DOSE:

Adults

The usual dosage is 2.5 mg, or lower if recommended by your doctor. A lower dose can be obtained by manually breaking a conventional tablet in half. The ZOMIG RAPIMELT 2.5 mg orally dispersible tablets cannot be broken in half. The dose should be taken as soon as your migraine appears, but it may be taken at any time during your migraine headache. Swallow your dose with water.

For ZOMIG RAPIMELT orally dispersible tablets, the blister pack should be peeled open as shown on the foil (tablets should not be pushed through the foil). The ZOMIG RAPIMELT tablet should be placed on the tongue, where it will dissolve with the saliva. Water is not needed for the dispersible tablet.

A second dose may be taken if your headache returns, but not sooner than 2 hours following the first tablet. For any attack where you have no response to the first dose, do not take a second dose without first consulting your doctor.

Do not administer more than 10 mg in any 24 hour period.

OVERDOSE:

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Although the vast majority of ZOMIG and ZOMIG RAPIMELT users have not experienced any significant problems, you should be aware that the following side effects may occur.

Commonly reported side effects of ZOMIG and ZOMIG RAPIMELT are:

- feeling sick
- vomiting
- dizziness
- tiredness
- weakness

ZOMIG may commonly cause drowsiness. Do not drive or operate machinery until you are sure that you are not drowsy.

Other common side effects include:

- muscle aches and pains

- difficulty swallowing
- dry mouth
- headache
- stomach pain

Uncommon side effects include:

- increase in the production of urine or in the frequency of urination

Tell your doctor of these symptoms at your next visit.

Migraineurs may be at risk of certain cerebrovascular events such as cerebral bleeding and stroke. In very rare cases, as with other drugs of this type, such diseases have been reported in association with the use of zolmitriptan.

In very rare cases, as with other drugs of this type (5HT₁ agonists), the following side effects have been reported:

- spasm of the blood vessels of the heart
- spasm of the blood vessels of the Gastro-Intestinal tract and spleen with possible infarctions

See the following table for what to do about serious side effects.

SERIOUS SIDE EFFECTS OF ZOMIG AND ZOMIG RAPIMELT, 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 (frequency greater than or equal to 1% but in less than 10% of patients)			
Irregular heart beat		✓	
Sensations of pain, pressure or tightness in the chest, neck, throat, jaw, arms, or legs			✓
Sensations of tingling, heat, heaviness or pressure			✓
Uncommon (frequency greater than or equal to 0.1% but in less than 1% of patients)			
Fast heart rate		✓	
Temporary increase in blood pressure		✓	
Rare (frequency greater than or equal to 0.01% but in less than 0.1% of patients)			
Shortness of breath, wheeziness, heart throbbing, allergic reactions including swelling of the eyelids, face, lips, mouth, tongue or neck; or a skin rash, itchy rash, skin lumps or hives, or swelling with fluid in the tissues			✓
Very rare (frequency in less than 0.01% of patients)			
Symptoms of a heart attack (chest pain, sweating, shortness of breath)			✓

SERIOUS SIDE EFFECTS OF ZOMIG AND ZOMIG RAPIMELT, 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	
Sudden or severe abdominal pain or bloody diarrhea			✓

For any unexpected effects while taking ZOMIG/ZOMIG RAPIMELT, contact your doctor or pharmacist.

HOW TO STORE IT

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

If your doctor decides to stop your treatment, return your medicine to the pharmacist for disposal. Do not take your medication after the expiry date on the package and blister foil. Return the tablets to your pharmacist for disposal.

REPORTING SUSPECTED SIDE EFFECTS
<p>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:</p> <ul style="list-style-type: none"> • Report online at www.healthcanada.gc.ca/medeffect • Call toll-free at 1-866-234-2345 • Complete a Canada Vigilance Reporting Form and: <ul style="list-style-type: none"> - Fax toll-free to 1-866-678-6789, or - Mail to: Canada Vigilance Program Health Canada Postal Locator 0701E Ottawa, ON K1A 0K9 <p>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.</p> <p><i>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.</i></p>

MORE INFORMATION

NOTE: This INFORMATION FOR THE CONSUMER leaflet provides you with the most current information at the time of printing.

For the most current information, the Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at:

www.astrazeneca.ca or by contacting the sponsor, AstraZeneca Canada Inc. at:

Customer Inquiries – 1 (800) 668-6000,

Renseignements – 1 (800) 461-3787.

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