

PART III: CONSUMER INFORMATION

Pr ZOLMITRIPTAN ODT

Zolmitriptan orally disintegrating tablet

This leaflet is part III of a three-part "Product Monograph" published when ZOLMITRIPTAN 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 ZOLMITRIPTAN ODT. 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 ZOLMITRIPTAN ODT which can only be obtained by prescription from your doctor. The decision to use ZOLMITRIPTAN ODT 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 ZOLMITRIPTAN ODT are appropriate for you.

What the medication is used for:

ZOLMITRIPTAN ODT belongs to a group of anti-migraine drugs called 5-HT₁ agonists. ZOLMITRIPTAN ODT is used to relieve your migraine headache and other associated symptoms of a migraine attack.

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

When it should not be used:

ZOLMITRIPTAN ODT should not be used if:

- you are allergic to zolmitriptan or any of the other ingredients in ZOLMITRIPTAN ODT (see "What the important nonmedicinal ingredients are");
- you have a history, or any symptoms or signs of a heart condition;
- 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:

ZOLMITRIPTAN ODT orally disintegrating tablet contains 2.5 mg of zolmitriptan as the active ingredient.

What the important nonmedicinal ingredients are:

ZOLMITRIPTAN ODT contains: aspartame, citric acid anhydrous, silica colloidal anhydrous, crospovidone, magnesium stearate, mannitol, silicified microcrystalline cellulose, sodium hydrogen carbonate, sweet orange flavour

What dosage forms it comes in:

ZOLMITRIPTAN ODT is supplied in orally disintegrating tablet in blister packs containing 6 tablets.

WARNINGS AND PRECAUTIONS

BEFORE you use ZOLMITRIPTAN ODT 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? 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)?
- 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 ZOLMITRIPTAN ODT too often, it may make your headaches worse. If this happens, your doctor may tell you to stop taking ZOLMITRIPTAN.

Use of ZOLMITRIPTAN ODT during pregnancy:

Do not use ZOLMITRIPTAN 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 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. The ZOLMITRIPTAN ODT 2.5 mg orally disintegrating 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.

For ZOLMITRIPTAN ODT orally disintegrating tablets, the blister pack should be peeled open as shown on the foil (tablets should not be pushed through the foil). The ZOLMITRIPTAN ODT orally disintegrating tablet should be placed on the tongue, where it will dissolve with the saliva. Water is not needed for the disintegrating 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, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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

Commonly reported side effects of zolmitriptan are:

- feeling sick
- vomiting
- dizziness
- tiredness
- weakness

Zolmitriptan may 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, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
	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, swelling of the eyelids, face, or lips; 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)			√
Sudden or severe abdominal pain or bloody diarrhea			√

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

HOW TO STORE IT

Keep your medicine in a safe place where children cannot reach it. ZOLMITRIPTAN ODT 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

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 obtained by contacting the sponsor, Sanis Health Inc. at:

Phone: 1-866-236-4076;
or quality@sanis.com

This leaflet was prepared by:

Sanis Health Inc.
1 President's Choice Circle
Brampton, Ontario
Canada, L6Y 5S5

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