

Pr **ZOMIG® NASAL SPRAY**
zolmitriptan

PART III: CONSUMER INFORMATION

This leaflet is part III of a three-part "Product Monograph" published when ZOMIG NASAL SPRAY was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ZOMIG NASAL SPRAY. 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 Nasal Spray which can only be obtained by prescription from your doctor. The decision to use ZOMIG Nasal Spray 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 Nasal Spray is appropriate for you.

WHAT THE MEDICATION IS USED FOR:

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

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

WHEN IT SHOULD NOT BE USED:

ZOMIG Nasal Spray should not be used if:

- you are allergic to zolmitriptan or any of the other ingredients in ZOMIG Nasal Spray (see "WHAT THE 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:

Each ZOMIG Nasal Spray device contains either 2.5 mg or 5 mg of zolmitriptan in a unit dose.

WHAT THE IMPORTANT NONMEDICINAL INGREDIENTS ARE:

Each ZOMIG Nasal Spray device contains: citric acid, disodium phosphate (dodecahydrate or dihydrate), and water.

WHAT DOSAGE FORMS IT COMES IN:

ZOMIG Nasal Spray is supplied as a single dose spray unit in a blue coloured plastic device, with a grey protection cap. Each Nasal Spray delivers either 2.5 or 5 mg of drug.

WARNINGS AND PRECAUTIONS

BEFORE you use ZOMIG Nasal Spray 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?
- 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)?

Use of ZOMIG Nasal Spray during pregnancy:

Do not use ZOMIG Nasal Spray 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 dose is a single nasal spray administration into one nostril.

If your headache comes back after your initial dose, a second dose may be administered anytime after 2 hours of administering the first dose. For any attack where you have no response to the first dose, do not take a second dose without prior consultation with your doctor.

Do not administer more than a total of 10 mg of ZOMIG in any 24-hour period.

The ZOMIG Nasal Spray unit consists of the following parts:

Protective Cover: This covers the nozzle to protect it. It must be removed before you use the nasal spray device (Figure 1A).

Nozzle: This is the part that you put into your nostril. The medicine comes out of a tiny hole in the top (Figure 1B).

Finger-grip: This is the part that you hold when you use the spray.

Plunger: This is the part that you press when you have inserted the nozzle comfortably into your nostril. This device works only once.

Steps for using ZOMIG Nasal Spray (Please read all steps prior to use):

1. Blow your nose gently before use. Remove the protective cover (Figure 1A). Hold the nasal spray gently with your fingers and thumb as shown in the picture (Figure 1B).

Do not press the plunger until you have put the nozzle into your nostril or you will lose the dose.



Figure 1

2. Block one nostril by pressing firmly on the side of your nose (Figure 2). Either nostril can be used.

Do not press the plunger yet.

Do not spray the contents of the device in your eyes.

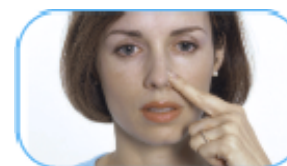


Figure 2

3. Put the nozzle (B) of the nasal spray device into the other nostril as far as feels comfortable (Figure 3). Tilt your head slightly as shown in the picture. Breathe in gently through your nose and at the same time press the plunger firmly with your thumb. The plunger may feel stiff and you may hear a click.



Figure 3

Keep your head slightly tilted back and remove the nozzle from your nose. Breathe gently through your mouth for 5-10 seconds. You may feel liquid in your nose. This is normal and will soon pass.

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 Nasal Spray users have not experienced any significant problems, you should be aware of the following side effects:

A very commonly reported side effect of ZOMIG Nasal Spray is disturbed taste that is normal and will pass soon.

Commonly reported side effects of ZOMIG Nasal Spray are:

- feeling sick
- vomiting
- dizziness
- tiredness
- weakness

ZOMIG 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
- discomfort inside the nose
- nose-bleed

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 NASAL SPRAY, 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, 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			√

For any unexpected effects while taking ZOMIG Nasal Spray, contact your doctor or pharmacist.

HOW TO STORE IT

Keep your medicine in a safe place where children cannot reach it. ZOMIG Nasal Spray 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. Return the unused nasal spray devices 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 0701C
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

NOTE: This CONSUMER INFORMATION 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.**

This leaflet was prepared by AstraZeneca Canada Inc., Mississauga, Ontario, L4Y 1M4

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