#### PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrMAR-ZOLMITRIPTAN zolmitriptan tablets

Read this carefully before you start taking **MAR-ZOLMITRIPTAN** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **MAR-ZOLMITRIPTAN**.

## **Serious Warnings and Precautions**

- **Risk of Heart Attack:** Serious heart events including heart attack have been reported within a few hours of starting treatment with MAR-ZOLMITRIPTAN. Do NOT use this medication if you have any form of coronary artery disease.
- **Heart Rhythm Problems:** Life-threatening instances of heart rhythm disturbances have been reported within a few hours of starting treatment with MAR-ZOLMITRIPTAN. This can be fatal.
- **Chest Pain:** MAR-ZOLMITRIPTAN may cause chest pain, even in patients without a history of coronary artery disease.
- **Risk of Stroke:** Bleeding in the brain and stroke have been reported in patients taking medications like MAR-ZOLMITRIPTAN. These conditions can be fatal.

If you think you are experiencing any of the above, contact your healthcare professional or get immediate medical help.

## What are MAR-ZOLMITRIPTAN used for?

MAR-ZOLMITRIPTAN is used in adults to relieve migraine headache and other associated symptoms of a migraine attack.

MAR-ZOLMITRIPTAN should not be used to prevent or reduce the number of attacks you experience. Only use MAR-ZOLMITRIPTAN to treat an actual migraine headache attack. How do MAR-ZOLMITRIPTAN work?

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

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MAR-ZOLMITRIPTAN:

Medicinal ingredients: zolmitriptan.

Non-medicinal ingredients: anhydrous lactose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate and the Film Coating ingredients containing the following: Hypromellose, Polyethylene glycol, Titanium dioxide and Yellow iron oxide.

# MAR-ZOLMITRIPTAN come in the following dosage forms:

MAR-ZOLMITRIPTAN: tablets, 2.5 mg.

### Do not use MAR-ZOLMITRIPTAN if:

- you are allergic to zolmitriptan or any of the other ingredients in MAR-ZOLMITRIPTAN (see "What are the ingredients in MAR-ZOLMITRIPTAN?")
- you have a history, or any signs or symptoms of a heart problem or condition
- you have ever had a heart attack or stroke
- you suffer from chest pain, occurring either on exertion or at rest
- you have severe or uncontrolled hypertension
- you are taking or have recently taken (within the last 24 hours) an ergotamine containing or ergot-like drug, or another triptan used to treat migraines
- you are taking or have recently taken (within 2 weeks) a monoamine oxidase inhibitor (MAOI)
- you have another type of headache, that is different from a migraine attack (if you are not sure, ask your healthcare professional. These include:
  - Hemiplegic migraines: these are migraine headaches where you have weakness on one side of your body.
  - Basilar migraines: these are migraine headaches that start in the lower part of the brain.
  - Ophthalmoplegic migraines: these are migraine headaches where you have pain around the eyes.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MAR-ZOLMITRIPTAN. Talk about any health conditions or problems you may have, including if you:

- have any liver problems
- are at risk of developing heart disease, risk factors include if you:
  - have high blood pressure
  - have high cholesterol
  - are obese
  - have diabetes
  - have a family history of heart disease
  - are a smoker
  - are a postmenopausal female
  - are a male over 40 years of age
- have a condition called Wolff-Parkinson-White syndrome

- have any other allergies or sensitivities
- have a history of epilepsy or structural brain lesions
- have a history of drug use
- · are pregnant, think you are pregnant or are planning to become pregnant
- are breastfeeding, or plan to breastfeed
- are over 65 years of age
- have a rare hereditary galactose intolerance such as Lapp lactase deficiency or glucosegalactose malabsorption, because MAR-ZOLMITRIPTAN tablets contain lactose

# Other warnings you should know about:

**Driving and Using Machines:** MAR-ZOLMITRIPTAN can cause sedation. Avoid driving or using machines until you know how the medication affects you.

**Overuse of MAR-ZOLMITRIPTAN:** As with other migraine treatments, using too much MAR-ZOLMITRIPTAN can cause daily headaches or make your migraine headaches worse. Ask your healthcare professional if you think this is the case for you. You may need to stop using MAR-ZOLMITRIPTAN to correct the problem.

**Risk of Eye Problems:** Long-term use of MAR-ZOLMITRIPTAN may cause eye problems. If you develop any problems with your eyes, tell your healthcare professional **right away**.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

### **Serious Drug Interactions**

Do NOT take MAR-ZOLMITRIPTAN if you are taking or have taken:

- In the last 24 hours, any medications that contain ergotamine (such as dihydroergotamine, methysergide).
- In the last 24 hours, other medications like MAR-ZOLMITRIPTAN (such as sumatriptan, naratriptan, almotriptan, rizatriptan or eletriptan).
- Within the last 2 weeks, a monoamine oxidase inhibitor (MAOI) (such as phenelzine sulfate, tranylcypromine sulfate, moclobemide).
- Any selective serotonin reuptake inhibitors (SSRI's) such as fluoxetine, sertraline, fluvoxamine, paroxetine, or any serotonin norepinephrine reuptake inhibitors (SNRIs) such as venlafaxine hydrochloride. These medications are often used in the treatment of depression.

# The following may interact with MAR-ZOLMITRIPTAN:

- medicines used to treat upset stomach or stomach ulcers (such as cimetidine)
- antibiotics from the quinolone family (such as ciprofloxacin)
- oral contraceptives
- propranolol, a beta blocker used to treat heart rhythm problems
- smoking or tobacco
- alcohol
- excessive amounts of green tea or green tea extract
- herbal remedies containing St John's wort

### **How to take MAR-ZOLMITRIPTAN:**

• Take MAR-ZOLMITRIPTAN exactly as your healthcare professional has told you to.

#### Usual dose:

### MAR-ZOLMITRIPTAN Tablets:

- The usual starting dose is 2.5 mg at the first sign of a migraine attack.
- Swallow the tablet with water.
- If your healthcare professional has recommended a smaller dose for you, the tablet can be broken in half.

If your headache returns and it has been at least 2 hours since you took your first dose, you may take a second dose. The maximum dose is 10 mg in any 24 hour period. If your first dose did not relieve your migraine headache, do not take a second dose without talking to your healthcare professional first.

#### Overdose:

If you think you, or a person you are caring for, have taken too much **MAR-ZOLMITRIPTAN**, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

## What are possible side effects from using MAR-ZOLMITRIPTAN?

These are not all the possible side effects you may have when taking MAR-ZOLMITRIPTAN. If you experience any side effects not listed here, tell your healthcare professional.

- feeling sick
- vomiting
- dizziness
- tiredness
- weakness
- muscle aches and pains
- difficulty swallowing

- dry mouth
- headache
- stomach pain
- increase in the production of urine or in the frequency of urination

Serious side effects and what to do about them								
Symptom / effect	Talk to your profess	Stop taking drug and get immediate						
Symptom / enect	Only if severe	In all cases	medical help					
COMMON			-					
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								
Fast heart rate		✓						
Temporary increase in blood pressure		✓						
RARE								
Allergic reaction: shortness of breath, sudden wheeziness, chest tightness, swelling of the eyelids, face, lips, mouth, tongue or neck, lumpy skin rash, or hives			<b>✓</b>					
VERY RARE								
Sudden or severe abdominal pain or bloody diarrhea			✓					
<b>Symptoms of a heart attack:</b> chest pain, sweating, shortness of breath			✓					
UNKNOWN FREQUENCY								
Serotonin toxicity: a reaction which may cause feelings of agitation or restlessness, flushing, muscle twitching, involuntary eye movements, heavy sweating, high body temperature (>38 °C), or rigid muscles.			✓					

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

# **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<u>canada.ca/drug-device-reporting</u>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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.

## Storage:

MAR-ZOLMITRIPTAN: Store between 15°C and 30°C.

Do not take your medication after the expiry date on the package and blister foil. If you have any leftover medication that you do not need or is expired, return the tablets to your pharmacist for disposal.

Keep out of reach and sight of children.

# If you want more information about MAR-ZOLMITRIPTAN:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website:
   (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website
   www.marcanpharma.com
   or by calling 1-855-627-2261.

This leaflet was prepared by Marcan Pharmaceuticals Inc

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