

PART III: CONSUMER INFORMATION

Pr SUMATRIPTAN DF

(sumatriptan succinate tablets)

This leaflet is part III of a three-part "Product Monograph" published when SUMATRIPTAN DF were approved for sale in Canada and is designed specifically for Consumers. (Please read this leaflet carefully before you take SUMATRIPTAN DF Tablets). This provides a summary of the information available on your medicine. This leaflet will not tell you everything about SUMATRIPTAN DF. Please do not throw away this leaflet until you have finished your medicine. You may need to read it again. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

The name of your medicine is SUMATRIPTAN DF (sumatriptan succinate) Tablets. They can be obtained only by prescription from your doctor. The decision to use SUMATRIPTAN DF Tablets 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 postmenopausal or a male over 40), you should tell your doctor, who should evaluate you for heart disease in order to determine if SUMATRIPTAN DF Tablets are appropriate for you.

What the medication is used for:

SUMATRIPTAN DF Tablets are intended to relieve your migraine headache and other associated symptoms of a migraine attack. **SUMATRIPTAN DF Tablets should not be used continuously to prevent or reduce the number of attacks you experience. Use SUMATRIPTAN DF Tablets 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. SUMATRIPTAN DF narrows these vessels and relieves the symptoms of migraine headache.

When it should not be used:

Do not use SUMATRIPTAN DF if:

- you are allergic to sumatriptan succinate or to any of the ingredients in SUMATRIPTAN DF (See "What the nonmedicinal ingredients are:").
- you have a history, or any symptoms or signs of a heart condition
- you have high blood pressure
- you are taking or have recently taken (within 2 weeks) a monoamine oxidase inhibitor (MAOI)
- you are taking or have recently taken (within 24 hours) an ergotamine-containing medication or its

- derivatives, or another triptan used to treat migraine
- you have any degree of liver disease

SUMATRIPTAN DF Tablets should not be used for the treatment of other types of headaches that are different from migraine attacks.

What the medicinal ingredient is:

Sumatriptan succinate

What the nonmedicinal ingredients are:

SUMATRIPTAN DF (25 mg, 50 mg and 100 mg Tablets):

colloidal silicon dioxide, lactose, magnesium stearate, microcrystalline cellulose and crospovidone

The film-coating for the 25 mg and 50 mg tablets for

SUMATRIPTAN DF consists of titanium dioxide, polydextrose, hydroxypropyl methylcellulose, triacetin, polyethylene glycol.

The film-coating for the 100 mg tablet for **SUMATRIPTAN DF** consists of titanium dioxide, polydextrose, hydroxypropyl methylcellulose, triacetin, polyethylene glycol, synthetic red iron oxide.

What dosage forms it comes in:

SUMATRIPTAN DF is available as pink 100 mg, white 50 mg, or white 25 mg film-coated tablets in bottles of 50 and blister packs of 6, 24 & 100 Tablets.

WARNINGS AND PRECAUTIONS

BEFORE you use SUMATRIPTAN DF talk to your doctor or pharmacist if:

- you are pregnant, think you might be pregnant, you are trying to become pregnant, you are using inadequate contraception or you are breast-feeding.
- you have any chest pain, heart disease, shortness of breath, or irregular heartbeats, you have had a heart attack, or you have angina.
- you have risk factors for heart disease (such as high blood pressure, high cholesterol, obesity, diabetes, smoking, strong family history of heart disease, or are you postmenopausal or a male over 40).
- you have ever had to stop taking this or any other medication because of an allergy or other problems, or you are allergic to sulpha-containing drugs.
- you are taking any medications, including migraine medications such as other triptans, 5-HT¹ agonists or those containing ergotamine, dihydroergotamine, or methysergide.
- you have ever experienced difficulty moving one side of your body when you have a headache.
- you have ever had a stroke, transient ischemic attacks (TIAs), or Raynaud's Syndrome.
- you are under 18 years of age

- you are over 65 years of age.
- you are taking any medication for depression (lithium, monoamine oxidase inhibitors or selective serotonin reuptake inhibitors (SSRIs), or serotonin noradrenaline reuptake inhibitors (SNRIs)
- you had, or you have any disease of the liver or kidney.
- you had, or you have epilepsy or seizures.
- this headache is different from your usual migraine attacks.

SUMATRIPTAN DF Tablets should not be used continuously to prevent or reduce the number of attacks you experience. Use SUMATRIPTAN DF Tablets only to treat an actual migraine headache attack.

If you use SUMATRIPTAN DF Tablets too often, it may make your headaches worse. If this happens, your doctor may tell you to stop taking SUMATRIPTAN DF Tablets.

The Use of SUMATRIPTAN DF During Pregnancy

Do not use SUMATRIPTAN DF Tablets if you are pregnant, think you might be pregnant, are trying to become pregnant, or are not using adequate contraception, unless you have discussed this with your doctor.

INTERACTIONS WITH THIS MEDICATION

Do not use SUMATRIPTAN DF Tablets if you are taking or have recently taken a monoamine oxidase inhibitors (MAOI) in the last 2 weeks, or any migraine medications containing ergotamine, ergot derivatives (such as dihydroergotamine, or methysergide), or other triptans used to treat migraine within 24 hours.

You should tell your doctor if you are taking or have recently taken any other medications (prescription, nonprescription or natural/herbal), before you start taking SUMATRIPTAN DF Tablets, especially any antidepressants such as selective serotonin reuptake inhibitors (SSRIs) and certain tricyclics.

PROPER USE OF THIS MEDICATION

The label on the container of your medicine or the leaflet inside should tell you how often to take a dose and the amount you should take in each dose. If it does not or you are not sure, ask your doctor or pharmacist. **DO NOT** take more medicine or take your medicine more often than you are told.

Usual dose:

Adults: Take as directed by your doctor. If the first tablet does not relieve your headache, do not take further doses of sumatriptan for the same attack. You may take pain medication other than ergotamine-containing preparations for further pain relief. SUMATRIPTAN DF Tablets may be taken for subsequent attacks.

SUMATRIPTAN DF Tablets can be taken at any time during your migraine headache.

If your symptoms come back, and it has been two hours since your first tablet, you may take a second tablet.

Do not take more than 200 mg in any 24 hour period.

SUMATRIPTAN DF Tablets may be taken with or without food. The tablet should be swallowed whole with water. It should not be crushed, chewed or split.

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

Like all medications, SUMATRIPTAN DF Tablets can cause some side effects. You may not experience any of them. For most patients these side effects are likely to be minor and temporary. However, some may be serious. Consult your doctor if you experience these or other side effects.

The most commonly reported side effects of SUMATRIPTAN DF Tablets are:

- pain, pressure or tightness in any part of the body, including chest and throat
- sensations of heaviness
- unusual sensations including numbness, tingling, heat/burning or cold
- flushing (redness of the face lasting for a short time)
- feeling sick or vomiting
- dizziness
- drowsiness
- tiredness
- weakness

As drowsiness may occur as a result of using SUMATRIPTAN DF Tablets, do not drive or operate machinery until you are sure that you are not drowsy.

Other side effects include:

- unusually slow or fast heartbeats, a feeling of irregular and/or forceful heartbeats
- visual disturbances, usually temporary (scotoma, nystagmus, flickering, diplopia).
- dystonia, (shaking, tremors or uncontrolled movements)
- loss of normal colouration in the fingers and toes.

Tell your doctor of these symptoms at your next visit. Very rarely,

some people have reported the following more serious side effects. For information on what to do if you experience these side effects, see the table at the end of this section.

- pain or tightness in the chest or throat
- loss of vision
- shortness of breath; wheeziness; chest tightening; swelling of eyelids, face, or lips; or a skin rash, skin lumps
- a seizure or fit
- sudden and/or severe abdominal pain
- persistent purple discolouration of hands or feet

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

Keep your medicine in a safe place where children cannot reach it. It may be harmful to children.

Keep your tablets in a cool, dry place (15°C to 30°C).

If your medication has expired (the expiration date is printed on the treatment pack), throw it away as instructed.

If your doctor decides to stop your treatment, do not keep any leftover medicine unless your doctor tells you to. Throw away your medicine as instructed.

Reminder:

REMEMBER: This medicine is for you. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptoms appear to be similar to yours.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptoms/effect		Talk with your doctor or pharmacist		Seek immediate medical emergency assistance
		Only if severe	In all cases	
Common	Unusual sensations including numbness, tingling, feeling hot or cold; pain, heaviness or pressure in any part of the body including chest and throat.	√		
Very rare	Symptoms of a heart attack [chest pain, sweating, shortness of breath]			√
Very rare	Unusually slow or fast heartbeats, or a feeling of irregular and/or forceful heartbeats	√		
Very rare	Allergic reactions [shortness of breath, sudden wheeziness, chest tightness, swelling of the eyelids, face or lips, lumpy skin rash or hives]			√
Very rare	Seizures [loss of consciousness with uncontrollable shaking("fit")]			√
Very rare	Lower abdominal pain and/or severe rectal bleeding.			√
Very rare	Raynaud's phenomenon [persistent purple discolouration of hands or feet]			√
Very rare	Loss of vision			√

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

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information:

3 ways to report:

- On online at Medeffect
- By calling at 1-866-234-2345 (toll-free)
- By completing a Consumer Side Effect Reporting Form and sending it by :
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels, Consumer Side Effect Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [MedEffect](#).

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.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting: Sivem Pharmaceuticals ULC at: 1-855-788-3153

HOW TO STORE IT

Or at: www.sivem.ca

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