PART III: CONSUMER INFORMATION

PrEFFIENT®
prasugrel (as prasugrel hydrochloride)

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

ABOUT THIS MEDICATION

What the medication is used for:
The reason that your doctor has prescribed EFFIENT for you is because you have experienced a heart attack or had unstable angina (chest pain). A heart attack or unstable angina can occur when fatty deposits in the arteries cause blood clots that block the flow of oxygen to your heart. Your doctor may have placed a stent to open a blocked or partially blocked artery in your heart that caused your heart attack or unstable angina.

What it does:
EFFIENT is in a class of prescription medications called antiplatelet agents. Antiplatelet agents reduce the ability of blood to clot. EFFIENT with aspirin reduces the risk of a future heart attack.

When it should not be used:
- If you have had a history of stroke or TIA. A TIA, also called a "ministroke", is a condition in which the stroke symptoms went away within 24 hours
- If you have severe liver disease or damage.
- If you have active bleeding conditions, such as bleeding from your stomach or intestines or brain.
- If you are breastfeeding
- If you are allergic to any of the substances contained in the tablets (see below).

What the medicinal ingredient is:
Prasugrel hydrochloride

What the nonmedicinal ingredients are:
Croscarmellose sodium, hypromellose, iron oxide red, iron oxide yellow, lactose, mannitol, microcrystalline cellulose, titanium dioxide, triacetin and vegetable magnesium stearate.

What dosage forms it comes in:
EFFIENT is available as a 10 mg (beige), non-scored, elongated hexagonal tablet.

WARNINGS AND PRECAUTIONS

EFFIENT increases the risk of bleeding.
- In patients 75 years of age or older, use is not recommended because of the increased risk of fatal bleeding and bleeding from blood vessels inside the head.
- In patients with body weight of less than 60 kg (132 lbs), use is not recommended because of the increased risk of major bleeding.

BEFORE you use EFFIENT tell your doctor about all of the following:
- **All your medical conditions.** Describe any history of bleeding conditions. Report any stomach ulcers, diverticulitis, or liver problems you may have and any recent severe injury or recent surgery.
- Allergies to medications including if you have had an allergic reaction to clopidogrel or ticlopidine.
- **All medicines you are taking or plan to take.** This includes prescription and non-prescription medicines, vitamins, and herbal supplements. Be sure to point out if you regularly take a non steroidal anti-inflammatory drug for example ibuprofen (Advil®, Motrin®), naproxen (Naprosyn®), or oral anticoagulants (blood thinners) such as warfarin (Coumadin™)*.
- **Any plans to have a surgical or dental procedure.** Your doctor or dentist may ask you to temporarily stop taking EFFIENT 7 days prior to surgery due to the risk of increased bleeding. Do not stop taking EFFIENT without talking to your cardiologist.
- If you are breast-feeding, pregnant, or are planning to get pregnant.
- If you are less than 18 years old.
- If you have had an allergic reaction to any of the substances contained in the EFFIENT tablets.

If you experience any allergic reaction including symptoms such as swelling mainly of the face and throat (angioedema), **stop** taking EFFIENT and seek **immediate** medical attention**.**

It is important that you tell all of your healthcare professionals that you are taking EFFIENT.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements.
Drugs that may interact with EFFIENT include: Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) and oral anticoagulants (blood thinners) such as warfarin.

PROPER USE OF THIS MEDICATION

It is important to take EFFIENT exactly as prescribed by your doctor. It is also important to get your refills on time so you do not run out of medicine.

Usual dose:

Your doctor will prescribe the right dose of EFFIENT for you. EFFIENT is usually started with a single 60 mg loading dose, Then, the usual dose is 10 mg daily.

- Take EFFIENT once a day by mouth, with or without food.
- Do not break your EFFIENT tablet. Talk to your healthcare professional if you have trouble swallowing pills.
- Continue taking acetylsalicylic acid (ASA) as directed by your doctor.
- Your doctor will decide how long you should take EFFIENT. **Stopping EFFIENT without informing your doctor may increase the chance of a heart attack or stroke or a clot forming in your stent**. Therefore you should inform your doctor immediately if you stop taking EFFIENT.

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.

Missed Dose:

If you miss your scheduled daily dose, take EFFIENT when you remember. If you forget your dose for an entire day, just resume taking EFFIENT at its usual dose the next day. Do not take two doses on the same day.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all antiplatelet medications, EFFIENT can increase the risk of bleeding. While taking EFFIENT, you may notice that you bruise more easily, are more likely to have nose bleeds, or have cuts that take longer to stop bleeding. Unlike these types of bleeding, some bleeding can be serious, even fatal. Bleeding, such as rectal bleeding or coughing up blood, should be investigated by your doctor as it may be a sign of an unsuspected tumour.

Tell your doctor about a rash that bothers you or that does not go away. If you notice any undesirable effects, especially during the first few weeks of treatments, including any not mentioned in the table below, promptly notify your doctor for assessment and follow-up.

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 call your doctor or pharmacist
		Only if severe	In all cases	
Common	Anaemia (shortness of breath, paleness, weakness)		✓	
	Bruising (that develops without known cause or grows in size)	✓		
	Bleeding in the stomach, intestine, or rectum (red or black stools)		✓	
	Vomit blood or your vomit looks like coffee grounds		✓	
	Rash	✓		
	Blood in urine		✓	
	Bleeding or bruising from a needle puncture	✓		
	Nose bleeds	✓		
Un-common	Bleeding in the eye		✓	
	Coughing up blood		✓	
	Gum bleeding	✓		
	Sudden severe headache		✓	
	Dizziness, lightheadedness		✓	

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Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
	Purplish spots on the skin or mucous membranes fever , yellowish colour of the eyes or skin, speech or visual changes, confusion, extreme tiredness		✓ (immediately)	
	Allergic reactions (including swelling of the face and throat)			✓

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

HOW TO STORE IT

- Keep EFFIENT in its original blister packaging and do not place your EFFIENT tablets in any other container.
- Store EFFIENT at room temperature between 15°C-30°C.
- Keep EFFIENT and all medicines out of the reach of children.

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 0701D
    Ottawa, Ontario
    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

For more information, please contact your healthcare professionals or pharmacist first, or Eli Lilly Canada Inc. at: 1-888-545-5972, or visit the website at www.lilly.ca.

The information in this document is current as of the last revision date shown below. For the most current information please visit our website or contact us directly.

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