

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.

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.

ABOUT THIS MEDICATION

What the medication is used for:

Your doctor prescribed EFFIENT because you

- have experienced a heart attack from a blocked artery or
- had unstable angina from a partially blocked artery.

Your doctor may have placed a stent to open the artery in your heart that caused these problems.

EFFIENT is used with ASA (Aspirin®)* to help prevent blood clots from forming within the arteries in your heart or stent, therefore reducing your risk of having a new heart attack.

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:

Do not take EFFIENT if you

- are allergic to EFFIENT or to any nonmedicinal ingredient in the formulation.
- have ever had a stroke or transient ischemic attack (TIA). A TIA, also called a "ministroke", is a condition in which the stroke symptoms went away within 24 hours.
- have severe liver disease or damage.
- have active bleeding conditions, such as bleeding from your stomach or intestines or brain.

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.

BEFORE you use EFFIENT, talk to your doctor, nurse or pharmacist if you:

- have a history of bleeding conditions, stomach ulcers, diverticulitis or liver problems.
- have had a recent severe injury or recent surgery (including dental procedures).
- have allergies to medications including if you have had an allergic reaction to clopidogrel or ticlopidine.
- **are planning 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.
- are breastfeeding, pregnant, or are planning to get pregnant.
- are less than 18 years old.
- have kidney disease or damage.
- have one of the following rare hereditary diseases:
 - Galactose intolerance,
 - Lapp lactase deficiency,
 - Glucose-galactose malabsorption.
 because lactose is a non-medicinal ingredient in EFFIENT.

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

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you regularly take, including prescription and non-prescription medicines, vitamins, minerals, natural supplements, or alternative medicines.

Drugs that may interact with EFFIENT include:

- Nonsteroidal Anti-Inflammatory Drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen (Advil®, Motrin®)*, naproxen (Naprosyn®, Aleve®)*.
- Oral anticoagulants (blood thinners) such as warfarin (Coumadin™)*.

- Fibrinolytics (drugs used to dissolve blood clots during treatment for a heart attack or lung clot). Examples include streptokinase, tissue plasminogen activators (tPAs) and tenecteplase (TNKase®)*.

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:

If you think you have taken too much EFFIENT, contact your doctor, nurse, pharmacist, 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 seek immediate medical help
		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		✓	
	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 0701E
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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