

# FACTS ABOUT EFFIENT® (PRASUGREL)

## WHAT IS EFFIENT?

Effient (pronounced EF-fee-ent) is a thienopyridine antiplatelet agent approved by the US Food and Drug Administration (FDA) to help reduce the risk of future thrombotic cardiovascular (CV) events, such as blood clots in a stent, in patients with acute coronary syndrome (ACS) managed with percutaneous coronary intervention (PCI).<sup>1</sup>

- PCI procedures are performed to open an artery blockage and can include the placement of a stent.<sup>2</sup>
- ACS is a form of cardiovascular disease that results from sudden insufficient blood supply to the heart and includes unstable angina (UA—heart-related chest pain at rest) or heart attack.<sup>3</sup>

## WHAT ARE THE DOSAGE FORMS AND STRENGTHS OF EFFIENT?

Effient is available in 5-mg and 10-mg tablets.<sup>1</sup>

## WHAT IS THE RECOMMENDED DOSING FOR ACS-PCI PATIENTS?

The loading dose (LD) of Effient is 60 mg and the maintenance dose (MD) is 10 mg once daily.

## HOW DOES EFFIENT WORK?

Effient and aspirin help keep platelets from sticking together and forming blood clots that block the patient's heart arteries or stent.<sup>4</sup>

## WHO SHOULD TAKE EFFIENT?

Effient is for patients who have had a heart attack or severe heart-related chest pain treated with PCI. Effient taken with aspirin helps reduce the risk of a future heart-related event, such as a heart attack or blood clot in the patient's stent.<sup>1</sup>

## IMPORTANT SAFETY INFORMATION

### What is the most important information patients should know about Effient?

Effient® (prasugrel) can cause bleeding. If patients have unexplained or excessive bleeding while on Effient, they should contact their doctor right away as some bleeding can be serious, and sometimes lead to death. Patients should not take Effient if they currently have abnormal bleeding, such as stomach or intestinal bleeding, bleeding in their head, or have a history of stroke, or "mini-stroke" (also known as transient ischemic attack or TIA), or if they are allergic to prasugrel or any of the ingredients in Effient.

Patients should get medical help right away if they suddenly have slurring of speech, weakness or numbness in one part of their body, blurry vision, and/or severe headache. These may be symptoms of a stroke or TIA. If patients have a stroke or TIA while taking Effient, their doctor will probably stop Effient.

Before having any surgery, patients should talk to their doctor about stopping Effient. If possible, patients should stop taking Effient at least 1 week (7 days) before any surgery, as instructed by their doctor who prescribed Effient.

Patients may also have a higher risk of bleeding if they take Effient and they: a) are age 75 or older, b) weigh less than 132 pounds, c) are taking anticoagulants (eg, warfarin) or regular daily use of NSAIDs, d) have had recent trauma, such as an accident or surgery, e) have severe liver problems, or f) have moderate to severe kidney problems, or g) have a stomach ulcer.

Patients should call their doctor right away if they have any of these signs or symptoms of bleeding: unexpected bleeding or bleeding that lasts a long time, bleeding that is severe or they cannot control, pink or brown urine, red or black stool, bruises that happen without a known cause or get larger, cough up blood or blood clots or vomit blood or their vomit looks like coffee grounds.

Patients should not stop taking Effient without talking to the doctor who prescribes it for them. People who are treated with angioplasty and have a stent, and stop taking Effient too soon, have a higher risk of a blood clot in the stent, having a heart attack, or dying.

## WHAT ARE THE CLINICAL BENEFITS OF EFFIENT® (PRASUGREL)?

In a head-to-head clinical trial (TRITON TIMI-38), Effient plus aspirin reduced the risk of heart-related events (CV death, heart attack, or stroke) compared with the FDA-approved dose of Plavix® (clopidogrel bisulfate) plus aspirin in patients with ACS managed with angioplasty. The difference in treatments was primarily driven by a significant reduction in non-fatal heart attacks, with no significant difference in cardiovascular death or nonfatal stroke. Effient had a higher rate of serious bleeding, including bleeding that led to death, when compared to Plavix.<sup>5</sup>

## IS EFFIENT INCLUDED IN CLINICAL PRACTICE GUIDELINES?

Effient is included in the guidelines for UA/NSTEMI and STEMI patients undergoing PCI:

- 2014 AHA/ACC NSTEMI-ACS Guidelines <sup>6</sup>
- 2013 ACCF/AHA STEMI Guidelines <sup>7,8</sup>
- 2011 ACCF/AHA/SCAI Guideline for PCI <sup>9,10</sup>

## IMPORTANT SAFETY INFORMATION (CONT.)

### WHAT SHOULD PATIENTS TELL THEIR DOCTOR BEFORE TAKING EFFIENT?

Patients should tell their doctor about all of their medical conditions, allergies, and medicines they are taking.

### WHAT ARE THE POSSIBLE SIDE EFFECTS OF EFFIENT?

Bleeding is the most common side effect of Effient.

TTP, a rare but life-threatening condition, has been reported with Effient, sometimes after a short time (less than 2 weeks). Patients should get medical attention right away if they develop the following unexpected symptoms of TTP: fever, weakness, yellowing of the skin or eyes, or if skin becomes very pale or dotted with purple spots.

Serious allergic reactions can happen with Effient, or if the patient has had a serious allergic reaction to the medicines Plavix® (clopidogrel) or ticlopidine. Patients should get medical help right away if they get any of these symptoms of a severe allergic reaction: swelling or hives of their face, lips, in or around their mouth, or throat; trouble breathing or swallowing; chest pain or pressure; dizziness or fainting.

Other side effects may occur.

Effient is available by prescription only. For more information, patients should talk to their healthcare provider or pharmacist.

**Patients are encouraged to report negative side effects of prescription drugs to the FDA. Patients can visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

For more information about Effient, please see the [Full Prescribing Information](#), including Boxed Warning regarding bleeding risk, and [Medication Guide](#).

## WHO DEVELOPED EFFIENT?

Daiichi Sankyo Company, Limited and Eli Lilly and Company have co-developed Effient. Effient was invented through a collaboration by scientists at Daiichi Sankyo and Ube Industries, Ltd.



Effient® is a registered trademark of Eli Lilly and Company.

Other product and company names mentioned herein are the trademarks of their respective owners.

©Daiichi Sankyo, Inc. and Lilly USA, LLC 7/2015. All Rights Reserved. PGMEDIAISI07MAY2015. PG97568.

REFER TO:

J. Scott MacGregor

Lilly USA

317-440-4699 (cell)

Jenn Silvent

Daiichi Sankyo

973-944-2160 (office)

973-479-9845 (cell)

- 1 Effient (prasugrel) prescribing information. Daiichi Sankyo, Inc. and Eli Lilly and Company.
- 2 CardioSmart, American College of Cardiology. "Heart Attack Treatment Guidelines," <https://www.cardiosmart.org/Heart-Conditions/Guidelines/Heart-Attack-Guidelines>. Last accessed May 29, 2015.
- 3 American Heart Association. Acute Coronary Syndrome. [http://www.heart.org/HEARTORG/Conditions/HeartAttack/AboutHeartAttacks/Acute-Coronary-Syndrome\\_UCM\\_428752\\_Article.jsp](http://www.heart.org/HEARTORG/Conditions/HeartAttack/AboutHeartAttacks/Acute-Coronary-Syndrome_UCM_428752_Article.jsp). Last accessed May 29, 2015.
- 4 Effient medication guide. Daiichi Sankyo, Inc. and Eli Lilly and Company.
- 5 Wiviott SD, Braunwald E, Angiolillo DJ, et al. Greater Clinical Benefit of More Intensive Oral Antiplatelet Therapy With Prasugrel in Patients With Diabetes Mellitus in the Trial to Assess Improvement in Therapeutic Outcomes by Optimizing Platelet Inhibition With Prasugrel–Thrombolysis in Myocardial Infarction 38. *Circulation*. 2008;118:1626-1636.
- 6 Amsterdam EA, Wenger NK, Brindis RG, et al. 2014 AHA/ACC Guideline for the Management of Patients With Non–ST-Elevation Acute Coronary Syndromes: Executive Summary, *J Am Coll Cardiol*. 2014;64(24):e139-e228.
- 7 O’Gara PT, Kushner FG, Ascheim DD, et al. 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction. *Circulation*. 2013;127:e362-e425.
- 8 O’Gara PT, Kushner FG, Ascheim DD, et al. 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction. *J Am Coll Cardiol*. 2013;61:e78-e140.
- 9 Levine GN, Bates ER, Blankenship JC, et al. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention. *Circulation*. 2011;124:e574-e651.
- 10 Levine GN, Bates ER, Blankenship JC, et al. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention. *J Am Coll Cardiol*. 2011;58:e44-e122.

