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Facts about Effient[®] (prasugrel)

What is Effient?

Effient[®] (prasugrel) (pronounced EF-fee-ent) is an antiplatelet agent approved by the U.S. Food and Drug Administration to help reduce the risk of future thrombotic cardiovascular events, including blood clots in a stent, in patients with acute coronary syndromes (ACS) managed with percutaneous coronary intervention (PCI).

- PCI procedures are performed to open an artery blockage and can include the placement of a stent.
- ACS is a form of cardiovascular disease and includes unstable angina (chest pain) and heart attack that result from sudden insufficient blood supply to the heart.¹

How Does Effient Work?

Effient prevents platelets, the blood particles responsible for clotting and stopping bleeding, from sticking or clumping together by blocking a specific receptor on the platelet surface. By keeping platelets from sticking together, Effient helps reduce the chance that arteries will be blocked by a clot.

What are the Clinical Benefits of Effient?

In a landmark, head-to-head clinical trial, Effient plus aspirin (ASA) was shown to be 19 percent more effective at reducing the rate of a combined endpoint of cardiovascular death, heart attack, or stroke than Plavix plus ASA in patients with ACS managed with PCI (absolute risk reduction = 2.2 percent, 9.9 percent vs. 12.1 percent, respectively). The difference between treatments was driven primarily by a reduction in heart attack with no difference on strokes and little difference on cardiovascular death. In addition, Effient reduced the risk

¹ American Heart Association. Association Between Hospital Process Performance and Outcomes Among Patients with Acute Coronary Syndromes. Available at: <http://www.americanheart.org/presenter.jhtml?identifier=3010002>. Accessed November 4, 2009.

of rare, but life-threatening stent-related clots by half when compared with Plavix (absolute risk reduction 0.9 percent, 0.9 percent vs. 1.8 percent, respectively). These benefits were accompanied by a higher risk of serious bleeding events, which in some cases were life-threatening or even fatal, in patients treated with Effient compared with Plavix (2.2 percent vs. 1.7 percent, respectively). The risk of serious bleeding events was highest in patients with a prior history of stroke or "mini" strokes known as TIAs, in patients 75 years of age or older, and in patients weighing less than 132 pounds.²

How Does Effient Work Differently in the Body than Plavix?

Effient and Plavix are metabolized differently to their active compounds. The active compound inhibits the platelet in the same manner.³

Who Should Take Effient?

Effient is indicated for patients with acute coronary syndromes managed with PCI, including stenting.

Effient should not be used in patients with active pathological bleeding or a history of transient ischemic attack or stroke. Effient should generally be discontinued in patients who develop a stroke while taking Effient. In patients 75 years of age or older, Effient is generally not recommended because of the increased risk of fatal and intracranial bleeding and uncertain benefit, except in high-risk situations (patients with diabetes or a history of heart attack).

Effient should not be started in patients likely to undergo urgent coronary artery bypass graft surgery (CABG).

How is Effient Taken?

Effient is taken orally and should be initiated with a single 60-mg loading dose, followed by a 10-mg daily dose. For patients weighing less than 132 pounds, a single 60-mg loading dose, followed by a 5-mg daily dose, may be considered.

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.

² Wiviott, S, Braunwald, E, et al. Prasugrel versus Clopidogrel in Patients with Acute Coronary Syndromes. *New England Journal of Medicine*. November 2007;357:2001-15.

³ Brandt, J, Payne, C, et al. A comparison of prasugrel and clopidogrel loading doses on platelet function: magnitude of platelet inhibition is relative to active metabolite formation. *American Heart Journal*. 2007;153:66.e9-66.e16.

What is the Safety Profile of Effient?

Important Safety Information about Effient

Antiplatelet medicines, including Effient, can increase the risk of 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 may lead to death. Patients should not take Effient if they have a stomach ulcer or other conditions that cause bleeding or if they have a history of stroke or “mini-stroke” (transient ischemic attack or TIA).

If patients are 75 or older, or if they weigh less than 132 pounds, or if they are taking anticoagulants (eg, warfarin) or taking NSAIDs (eg, ibuprofen or naproxen) for a long time, they should talk to their doctor, as they may be at an increased risk of bleeding.

If patients plan to have surgery or a dental procedure, they should tell their doctors that they are taking Effient.

Patients should not stop taking Effient without first talking to the doctor who prescribed it for them, as this may result in increased risk of a clot in their stent, a heart attack or death.

Patients should get medical attention right away if they develop any of the following unexpected symptoms: fever, weakness, yellowing of the skin or eyes, or if skin becomes very pale or dotted with purple spots. These symptoms may be signs of a rare but potentially life-threatening condition called TTP, which has been reported with other medicines in this class that are like Effient, sometimes after a short time (less than 2 weeks).

For more information about Effient including prescribing information, please visit www.Effient.com.

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