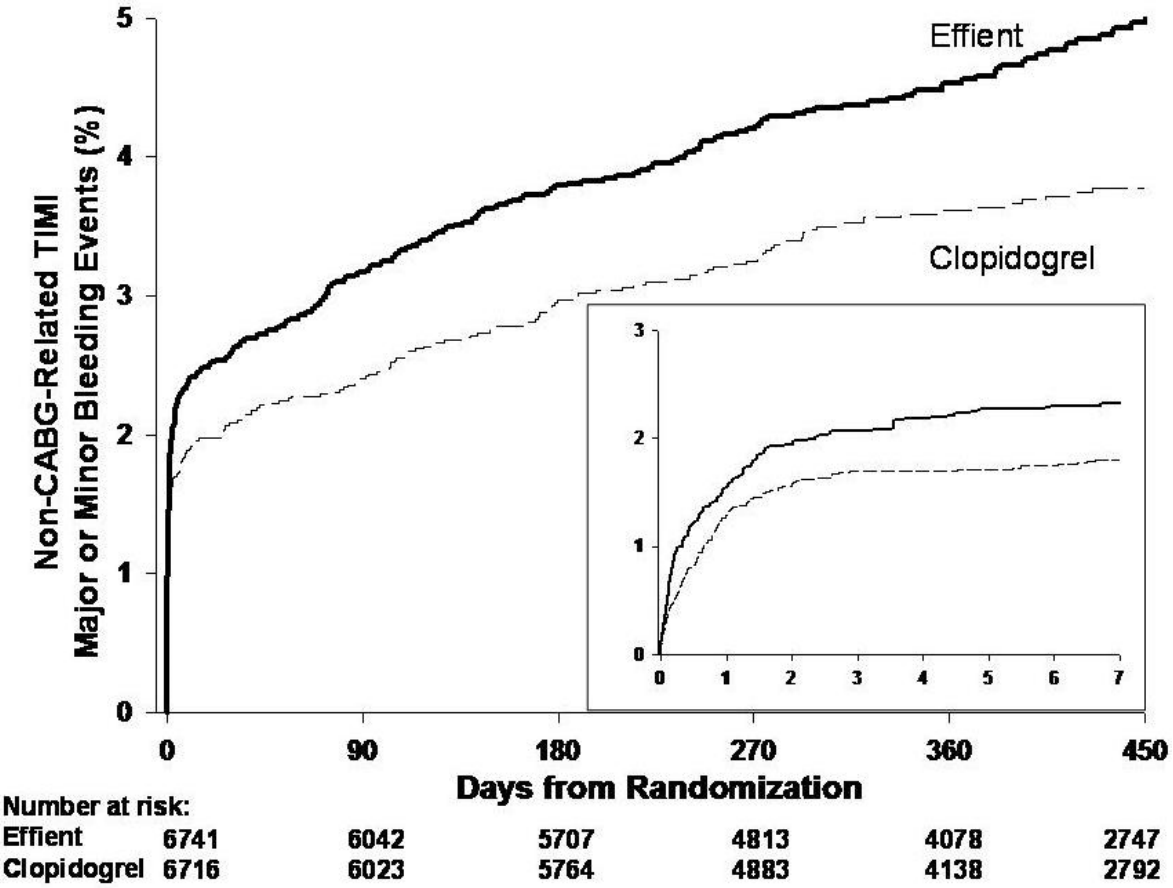
Figure 1: Non-CABG-Related TIMI Major or Minor Bleeding Events



Number at risk:						
Effient	6741	6042	5707	4813	4078	2747
Clopidogrel	6716	6023	5764	4883	4138	2792

Suspect bleeding in any patient who is hypotensive and has recently undergone coronary angiography, PCI, CABG, or other surgical procedures even if the patient does not have overt signs of bleeding.

Do not use Effient in patients with active bleeding, prior TIA or stroke *[see Contraindications (4.1, 4.2)]*.

Other risk factors for bleeding are:

- Age ≥75 years. Because of the risk of bleeding (including fatal bleeding) and uncertain effectiveness in patients ≥75 years of age, use of Effient is generally not recommended in these patients, except in high-risk situations (patients with diabetes or history of myocardial infarction) where its effect appears to be greater and its use may be considered *[see Adverse Reactions (6.1), Use in Specific Populations (8.5), Clinical Pharmacology (12.3), and Clinical Studies (14)]*.
- CABG or other surgical procedure *[see Warnings and Precautions (5.2)]*.
- Body weight <60 kg. Consider a lower (5 mg) maintenance dose *[see Dosage and Administration (2), Adverse Reactions (6.1), and Use in Specific Populations (8.6)]*.
- Propensity to bleed (e.g., recent trauma, recent surgery, recent or recurrent gastrointestinal (GI) bleeding, active peptic ulcer disease, severe hepatic impairment, or moderate to severe renal impairment) *[see Adverse Reactions (6.1) and Use in Specific Populations (8.7, 8.8)]*.
- Medications that increase the risk of bleeding (e.g., oral anticoagulants, chronic use of nonsteroidal anti-inflammatory drugs [NSAIDs], and fibrinolytic agents). Aspirin and heparin were commonly used in TRITON-TIMI 38 *[see Drug Interactions (7.1, 7.2, 7.4) and Clinical Studies (14)]*.

Thienopyridines inhibit platelet aggregation for the lifetime of the platelet (7-10 days), so withholding a dose will not be useful in managing a bleeding event or the risk of bleeding associated with an invasive procedure. Because the half-life of prasugrel's active metabolite is short relative to the lifetime of the platelet, it may be possible to restore hemostasis by administering exogenous platelets; however, platelet transfusions within 6 hours of the loading dose or 4 hours of the maintenance dose may be less effective.

5.2 Coronary Artery Bypass Graft Surgery-Related Bleeding

The risk of bleeding is increased in patients receiving Effient who undergo CABG. If possible, Effient should be discontinued at least 7 days prior to CABG.

Of the 437 patients who underwent CABG during TRITON-TIMI 38, the rates of CABG-related TIMI Major or Minor bleeding were 14.1% in the Effient group and 4.5% in the clopidogrel group *[see Adverse Reactions (6.1)]*. The higher risk for bleeding events in patients treated with Effient persisted up to 7 days from the most recent dose of study drug. For patients receiving a thienopyridine within 3 days prior to CABG, the frequencies of TIMI Major or Minor bleeding were 26.7% (12 of 45 patients) in the Effient group, compared with 5.0% (3 of 60 patients) in the clopidogrel group. For patients who received their last dose of thienopyridine within 4 to 7 days prior to CABG, the frequencies decreased to 11.3% (9 of 80 patients) in the prasugrel group and 3.4% (3 of 89 patients) in the clopidogrel group.

Do not start Effient in patients likely to undergo urgent CABG. CABG-related bleeding may be treated with transfusion of blood products, including packed red blood cells and platelets; however, platelet transfusions within 6 hours of the loading dose or 4 hours of the maintenance dose may be less effective.

5.3 Discontinuation of Effient

Discontinue thienopyridines, including Effient, for active bleeding, elective surgery, stroke, or TIA. The optimal duration of thienopyridine therapy is unknown. In patients who are managed with PCI and stent placement, premature discontinuation of any antiplatelet medication, including thienopyridines, conveys an increased risk of stent thrombosis, myocardial infarction, and death. Patients who require premature discontinuation of a thienopyridine will be at increased risk for cardiac events. Lapses in therapy should be avoided, and if thienopyridines must be temporarily discontinued because of an adverse event(s), they should be restarted as soon as possible *[see Contraindications (4.1, 4.2) and Warnings and Precautions (5.1)]*.

5.4 Thrombotic Thrombocytopenic Purpura (TTP)

TTP has been reported with the use of Effient. TTP can occur after a brief exposure (<2 weeks). TTP is a serious condition that can be fatal and requires urgent treatment, including plasmapheresis (plasma exchange). TTP is characterized by thrombocytopenia, microangiopathic hemolytic anemia (schistocytes [fragment red blood cells] seen on peripheral smear), neurological findings, renal dysfunction, and fever *[see Adverse Reactions (6.2)]*.

5.5 Hypersensitivity Including Angioedema

Hypersensitivity including angioedema has been reported in patients receiving Effient, including patients with a history of hypersensitivity reaction to other thienopyridines *[see Contraindications (4.3) and Adverse Reactions (6.2)]*.

6 ADVERSE REACTIONS

The following serious adverse reactions are also discussed elsewhere in the labeling:

- Bleeding *[see Boxed Warning and Warnings and Precautions (5.1, 5.2)]*
- Thrombotic Thrombocytopenic Purpura *[see Warnings and Precautions (5.4)]*
- Hypersensitivity Including Angioedema *[see Warnings and Precautions (5.5)]*

6.1 Clinical Trials Experience

Safety in patients with ACS undergoing PCI was evaluated in a clopidogrel-controlled study, TRITON-TIMI 38, in which 6741 patients were treated with Effient (60 mg loading dose and 10 mg once daily) for a median of 14.5 months (5802 patients were treated for over 6 months; 4136 patients were treated for more than 1 year). The population treated with Effient was 27 to 96 years of age, 25% female, and 92% Caucasian. All patients in the TRITON-TIMI 38 study were to receive aspirin. The dose of clopidogrel in this study was a 300 mg loading dose and 75 mg once daily.

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with the rates observed in other clinical trials of another drug and may not reflect the rates observed in practice.

Drug Discontinuation

The rate of study drug discontinuation because of adverse reactions was 7.2% for Effient and 6.3% for clopidogrel. Bleeding was the most common adverse reaction leading to study drug discontinuation for both drugs (2.5% for Effient and 1.4% for clopidogrel).

Bleeding

Bleeding Unrelated to CABG Surgery

In TRITON-TIMI 38, overall rates of TIMI Major or Minor bleeding adverse reactions unrelated to coronary artery bypass graft surgery (CABG) were significantly higher on Effient than on clopidogrel, as shown in Table 1.

Table 1: Non-CABG-Related Bleeding* (TRITON-TIMI 38)

	Effient (%) (N=6741)	**Clopidogrel (%) (N=6716)**
TIMI Major or Minor bleeding	4.5	3.4
TIMI Major bleeding†	2.2	1.7
Life-threatening	1.3	0.8
Fatal	0.3	0.1
Symptomatic intracranial hemorrhage (ICH)	0.3	0.3
Requiring inotropes	0.3	0.1
Requiring surgical intervention	0.3	0.3
Requiring transfusion (≥4 units)	0.7	0.5
TIMI Minor bleeding†	2.4	1.9

* Patients may be counted in more than one row.

† See 5.1 for definition.

Figure 1 demonstrates non-CABG-related TIMI Major or Minor bleeding. The bleeding rate is highest initially, as shown in Figure 1 (inset: Days 0 to 7) *[see Warnings and Precautions (5.1)]*.

Bleeding by Weight and Age

In TRITON-TIMI 38, non-CABG-related TIMI Major or Minor bleeding rates in patients with the risk factors of age ≥75 years and weight <60 kg are shown in Table 2.

Table 2: Bleeding Rates for Non-CABG-Related Bleeding by Weight and Age (TRITON-TIMI 38)

	Major/Minor		**Fatal**	
	Effient* (%)	**Clopidogrel† (%)**	**Effient* (%)**	**Clopidogrel† (%)**
Weight <60 kg (N=308 Effient, N=356 clopidogrel)	10.1	6.5	0.0	0.3
Weight ≥60 kg (N=6373 Effient, N=6299 clopidogrel)	4.2	3.3	0.3	0.1
Age <75 years (N=5850 Effient, N=5822 clopidogrel)	3.8	2.9	0.2	0.1
Age ≥75 years (N=891 Effient, N=894 clopidogrel)	9.0	6.9	1.0	0.1

* 10 mg Effient maintenance dose

† 75 mg clopidogrel maintenance dose

Bleeding Related to CABG

In TRITON-TIMI 38, 437 patients who received a thienopyridine underwent CABG during the course of the study. The rate of CABG-related TIMI Major or Minor bleeding was 14.1% for the Effient group and 4.5% in the clopidogrel group (see Table 3). The higher risk for bleeding adverse reactions in patients treated with Effient persisted up to 7 days from the most recent dose of study drug.

Table 3: CABG-Related Bleeding* (TRITON-TIMI 38)

	Effient (%) (N=213)	Clopidogrel (%) (N=224)
TIMI Major or Minor bleeding	14.1	4.5
TIMI Major bleeding	11.3	3.6
Fatal	0.9	0
Reoperation	3.8	0.5
Transfusion of ≥5 units	6.6	2.2
Intracranial hemorrhage	0	0
TIMI Minor bleeding	2.8	0.9

* Patients may be counted in more than one row.

Bleeding Reported as Adverse Reactions
Hemorrhagic events reported as adverse reactions in TRITON-TIMI 38 were, for Effient and clopidogrel, respectively: epistaxis (6.2%, 3.3%), gastrointestinal hemorrhage (1.5%, 1.0%), hemoptysis (0.6%, 0.5%), subcutaneous hematoma (0.5%, 0.2%), post-procedural hemorrhage (0.5%, 0.2%), retroperitoneal hemorrhage (0.3%, 0.2%), pericardial effusion/hemorrhage/tamponade (0.3%, 0.2%), and retinal hemorrhage (0.0%, 0.1%).

Malignancies
During TRITON-TIMI 38, newly diagnosed malignancies were reported in 1.6% and 1.2% of patients treated with prasugrel and clopidogrel, respectively. The sites contributing to the differences were primarily colon and lung. In another Phase 3 clinical study of ACS patients not undergoing PCI, in which data for malignancies were prospectively collected, newly diagnosed malignancies were reported in 1.8% and 1.7% of patients treated with prasugrel and clopidogrel, respectively. The site of malignancies was balanced between treatment groups except for colorectal malignancies. The rates of colorectal malignancies were 0.3% prasugrel, 0.1% clopidogrel and most were detected during investigation of GI bleed or anemia. It is unclear if these observations are causally related, are the result of increased detection because of bleeding, or are random occurrences.

Other Adverse Events
In TRITON-TIMI 38, common and other important nonhemorrhagic adverse events were, for Effient and clopidogrel, respectively: severe thrombocytopenia (0.06%, 0.04%), anemia (2.2%, 2.0%), abnormal hepatic function (0.22%, 0.27%), allergic reactions (0.36%, 0.36%), and angioedema (0.06%, 0.04%). Table 4 summarizes the adverse events reported by at least 2.5% of patients.

Table 4: Non-Hemorrhagic Treatment Emergent Adverse Events Reported by at Least 2.5% of Patients in Either Group

	Effient (%) (N=6741)	Clopidogrel (%) (N=6716)
Hypertension	7.5	7.1
Hypercholesterolemia/Hyperlipidemia	7.0	7.4
Headache	5.5	5.3
Back pain	5.0	4.5
Dyspnea	4.9	4.5
Nausea	4.6	4.3
Dizziness	4.1	4.6
Cough	3.9	4.1
Hypotension	3.9	3.8
Fatigue	3.7	4.8
Noncardiac chest pain	3.1	3.5
Atrial fibrillation	2.9	3.1
Bradycardia	2.9	2.4
Leukopenia (<4 x 10^9 WBC*/L)	2.8	3.5
Rash	2.8	2.4
Pyrexia	2.7	2.2
Peripheral edema	2.7	3.0

	Effient (%) (N=6741)	Clopidogrel (%) (N=6716)
Pain in extremity	2.6	2.6
Diarrhea	2.3	2.6

* WBC = white blood cell

6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of Effient. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Blood and lymphatic system disorders — thrombocytopenia, thrombotic thrombocytopenic purpura (TTP) *[see Warnings and Precautions (5.4) and Patient Counseling Information (17)]*

Immune system disorders — hypersensitivity reactions including anaphylaxis *[see Contraindications (4.3)]*

7 DRUG INTERACTIONS

7.1 Warfarin

Coadministration of Effient and warfarin increases the risk of bleeding *[see Warnings and Precautions (5.1) and Clinical Pharmacology (12.3)]*.

7.2 Nonsteroidal Anti-Inflammatory Drugs

Coadministration of Effient and NSAIDs (used chronically) may increase the risk of bleeding *[see Warnings and Precautions (5.1)]*.

7.3 Opioids

As with other oral $P2Y_{12}$ inhibitors, coadministration of opioid agonists delay and reduce the absorption of prasugrel's active metabolite presumably because of slowed gastric emptying *[see Clinical Pharmacology (12.3)]*. Consider the use of a parenteral anti-platelet agent in acute coronary syndrome patients requiring coadministration of morphine or other opioid agonists.

7.4 Other Concomitant Medications

Effient can be administered with drugs that are inducers or inhibitors of cytochrome P450 enzymes *[see Clinical Pharmacology (12.3)]*.

Effient can be administered with aspirin (75 mg to 325 mg per day), heparin, GPIIb/IIIa inhibitors, statins, digoxin, and drugs that elevate gastric pH, including proton pump inhibitors and H_2 blockers *[see Clinical Pharmacology (12.3)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no data with Effient use in pregnant women to inform a drug-associated risk. No structural malformations were observed in animal reproductive and developmental toxicology studies when rats and rabbits were administered prasugrel during organogenesis at doses of up to 30 times the recommended therapeutic exposures in humans *[see Data].* Due to the mechanism of action of Effient, and the associated identified risk of bleeding, consider the benefits and risks of Effient and possible risks to the fetus when prescribing Effient to a pregnant woman *[see Boxed Warning and Warnings and Precautions (5.1, 5.3)]*.

The background risk of major birth defects and miscarriage for the indicated population is unknown. The background risk in the U.S. general population of major birth defects is 2-4% and of miscarriage is 15-20% of clinically recognized pregnancies.

Data

Animal Data

In embryo-fetal developmental toxicology studies, pregnant rats and rabbits received prasugrel at maternally toxic oral doses equivalent to more than 40 times the human exposure. A slight decrease in fetal body weight was observed, but there were no structural malformations in either species. In prenatal and postnatal rat studies, maternal treatment with prasugrel had no effect on the behavioral or reproductive development of the offspring at doses greater than 150 times the human exposure.

8.2 Lactation

Risk Summary

There is no information regarding the presence of prasugrel in human milk, the effects on the breastfed infant, or the effects on milk production. Metabolites of prasugrel were found in rat milk *[see Data]*. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Effient and any potential adverse effects on the breastfed child from Effient or from the underlying maternal condition.

Data

Animal Data

Following a 5 mg/kg oral dose of [^{14}C]-prasugrel to lactating rats, metabolites of prasugrel were detected in the maternal milk and blood.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

In a randomized, placebo-controlled trial, the primary objective of reducing the rate of vaso-occlusive crisis (painful crisis or acute chest syndrome) in pediatric patients, aged 2 to less than 18 years, with sickle cell anemia was not met.

8.5 Geriatric Use

In TRITON-TIMI 38, 38.5% of patients were ≥65 years of age and 13.2% were ≥75 years of age. The risk of bleeding increased with advancing age in both treatment groups, although the relative risk of bleeding (Effient compared with clopidogrel) was similar across age groups.

Patients ≥75 years of age who received Effient 10 mg had an increased risk of fatal bleeding events (1.0%) compared to patients who received clopidogrel (0.1%). In patients ≥75 years of age, symptomatic intracranial hemorrhage occurred in 7 patients (0.8%) who received Effient and in 3 patients (0.3%) who received clopidogrel. Because of the risk of bleeding, and because effectiveness is uncertain in patients ≥75 years of age *[see Clinical Studies (14)]*, use of Effient is generally not recommended in these patients, except in high-risk situations (diabetes and past history of myocardial infarction) where its effect appears to be greater and its use may be considered *[see Warnings and Precautions (5.1), Clinical Pharmacology (12.3), and Clinical Studies (14)]*.

8.6 Low Body Weight

In TRITON-TIMI 38, 4.6% of patients treated with Effient had body weight <60 kg. Individuals with body weight <60 kg had an increased risk of bleeding and an increased exposure to the active metabolite of prasugrel *[see Dosage and Administration (2), Warnings and Precautions (5.1), and Clinical Pharmacology (12.3)]*. Consider lowering the maintenance dose to 5 mg in patients <60 kg. The effectiveness and safety of the 5 mg dose have not been prospectively studied *[see Dosage and Administration (2) and Clinical Pharmacology (12.3)]*.

8.7 Renal Impairment

No dosage adjustment is necessary for patients with renal impairment. There is limited experience in patients with end-stage renal disease, but such patients are generally at higher risk of bleeding *[see Warnings and Precautions (5.1) and Clinical Pharmacology (12.3)]*.

8.8 Hepatic Impairment

No dosage adjustment is necessary in patients with mild to moderate hepatic impairment (Child-Pugh Class A and B). The pharmacokinetics and pharmacodynamics of prasugrel in patients with severe hepatic disease have not been studied, but

Bleeding

Inform patients that they:

- will bruise and bleed more easily.
- will take longer than usual to stop bleeding.
- should report any unanticipated, prolonged, or excessive bleeding, or blood in their stool or urine *[see Warnings and Precautions (5.1)]*.

Thrombotic Thrombocytopenic Purpura

- Inform patients that TTP is a rare but serious condition that has been reported with Effient.
- Instruct patients to get prompt medical attention if they experience symptoms of TTP that cannot otherwise be explained *[see Warnings and Precautions (5.4)]*.

Hypersensitivity

Inform patients that they may have hypersensitivity reactions and to seek immediate medical attention if any signs and symptoms of a hypersensitivity reaction occur. Patients who have had hypersensitivity reactions to other thienopyridines may have hypersensitivity reactions to Effient.

Invasive Procedures

Instruct patients to:

- inform physicians and dentists that they are taking Effient before any invasive procedure is scheduled *[see Warnings and Precautions (5.1)]*.
- tell the doctor performing the invasive procedure to talk to the prescribing healthcare professional before stopping Effient.

Concomitant Medications

Ask patients to list all prescription medications, over-the-counter medications, or dietary supplements they are taking or plan to take so the physician knows about other treatments that may affect bleeding risk (e.g., warfarin and NSAIDs) *[see Drug Interactions (7.1, 7.2)].*

Manufactured by Daiichi Sankyo, Inc., Basking Ridge, NJ 07920

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USPI-EFF-MMYY-rXXX

Medication Guide

EFFIENT® (Ef´-fee-ent)

(prasugrel) tablets

What is the most important information I should know about Effient?

Effient is used to lower your chance of having a heart attack or other serious problems with your heart or blood vessels. But, Effient can cause bleeding, which can be serious, and sometimes lead to death. You should not start to take Effient if it is likely that you will have heart bypass surgery (coronary artery bypass graft surgery or CABG) right away. You have a higher risk of bleeding if you take Effient and then have heart bypass surgery.

What is Effient?

Effient is a prescription medicine used to treat people who:

- have had a heart attack or severe chest pain that happens when your heart does not get enough oxygen, and
- have been treated with a procedure called "angioplasty" (also called balloon angioplasty).

Effient is used to lower your chance of having another serious problem with your heart or blood vessels, such as another heart attack, a stroke, blood clots in your stent, or death.

Platelets are blood cells that help with normal blood clotting. Effient helps prevent platelets from sticking together and forming a clot that can block an artery or a stent.

It is not known if Effient is safe and works in children.

Who should not take Effient?

- **Do not take Effient if you:**
  - currently have abnormal bleeding, such as stomach or intestinal bleeding, or bleeding in your head
  - have had a stroke or "mini-stroke" (also known as transient ischemic attack or TIA)
  - are allergic to prasugrel or any of the ingredients in Effient. See the end of this Medication Guide for a list of ingredients in Effient.
- **Get medical help right away if you think you may be having a stroke or TIA. Symptoms that you may be having a stroke or TIA include:**
  - **sudden slurring of speech,**
  - **sudden weakness or numbness in one part of your body,**
  - **sudden blurry vision, or sudden severe headache.**
- **If you have a stroke or TIA while taking Effient, your doctor will probably stop your Effient. Follow your doctor's instructions about stopping Effient. Do not stop taking Effient unless your doctor tells you to.**
- **Before having any surgery, you should talk to your doctor about stopping Effient. If possible, Effient should be stopped at least 1 week (7 days) before any surgery, as instructed by the doctor who prescribed Effient for you.**

Your risk of bleeding while taking Effient may be higher if you also:

- have had trauma, such as an accident or surgery
- have stomach or intestine bleeding that is recent or keeps coming back, or you have a stomach ulcer
- have severe liver problems
- have moderate to severe kidney problems
- weigh less than 132 pounds
- take other medicines that increase your risk of bleeding, including:
  - warfarin sodium (Coumadin*, Jantoven*)
  - a medicine that contains heparin
  - other medicines to prevent or treat blood clots
  - regular daily use of nonsteroidal anti-inflammatory drugs (NSAIDs)

Tell your doctor if you take any of these medicines. Ask your doctor if you are not sure if your medicine is one listed above.

- Effient increases your risk of bleeding because it lessens the ability of your blood to clot. While you take Effient:
  - you will bruise and bleed more easily

- you are more likely to have nose bleeds
- it will take longer for any bleeding to stop

- Call your doctor right away if you have any of these signs or symptoms of bleeding:
  - unexpected bleeding or bleeding that lasts a long time
  - bleeding that is severe or you cannot control
  - pink or brown urine
  - red or black stool (looks like tar)
  - bruises that happen without a known cause or get larger
  - cough up blood or blood clots
  - vomit blood or your vomit looks like "coffee grounds"
- **Do not stop taking Effient without talking to the doctor who prescribes it for you. 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. If you must stop Effient because of bleeding, your risk of a heart attack may be higher. See "What are the possible side effects of Effient?" for more information about side effects.**

What should I tell my doctor before taking Effient?

Before you take Effient, tell your doctor about all of your medical conditions, including if you:

- have any bleeding problems.
- have had a stroke or "mini-stroke" (also known as transient ischemic attack or TIA).
- are allergic to any medicines, including clopidogrel (Plavix*) or ticlopidine hydrochloride.
- have a history of stomach ulcers, colon polyps, diverticulosis.
- have liver problems.
- have kidney problems.
- have had any recent severe injury or surgery.
- plan to have surgery or a dental procedure. See "What is the most important information I should know about Effient?"
- are pregnant, or are planning to get pregnant. It is not known if Effient will harm your baby.
- are breastfeeding. It is not known if Effient passes into your breast milk. You and your doctor should decide if you will take Effient or breastfeed. You should not do both without talking with your doctor.

Tell all of your doctors and dentists that you are taking Effient. They should talk to the doctor who prescribed Effient for you, before you have **any** surgery or invasive procedure.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Certain medicines may increase your risk of bleeding. See "What is the most important information I should know about Effient?"

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

How should I take Effient?

- Take Effient exactly as prescribed by your doctor.
- Take Effient one time each day.
- You can take Effient with or without food.
- Do not split Effient tablets.
- Take Effient with aspirin as instructed by your doctor.
- Your doctor will decide how long you should take Effient. Do not stop taking Effient without first talking to the doctor who prescribed it for you. See "What is the most important information I should know about Effient?"
- If you miss a dose, take Effient as soon as you remember. If it is almost time for your next dose, skip the missed dose. Just take the next dose at your regular time. Do not take two doses at the same time unless your doctor tells you to.
- If you take too much Effient, call your local emergency room or poison control center right away.

- Call your doctor or healthcare provider right away if you fall or injure yourself, especially if you hit your head. Your doctor or healthcare provider may need to check you.

What are the possible side effects of Effient?

Effient can cause serious side effects, including:

- **See "What is the most important information I should know about Effient?"**
- **A blood clotting problem called thrombotic thrombocytopenic purpura (TTP).** TTP can happen with Effient, sometimes after a short time (less than 2 weeks). TTP is a blood clotting problem where blood clots form in blood vessels and can happen all over the body. TTP needs to be treated in a hospital right away, because you may die. Get medical help right away if you have any of these symptoms and they cannot be explained by another medical condition:
  - purplish spots called purpura on the skin or mucous membranes (such as on the mouth) due to bleeding under the skin
  - paleness or jaundice (a yellowish color of the skin or eyes)
  - feeling tired or weak
  - fever
  - fast heart rate or feeling short of breath
  - headache, speech changes, confusion, coma, stroke, or seizure
  - low amount of urine or urine that is pink-tinged or has blood in it
  - stomach area (abdominal) pain, nausea, vomiting, or diarrhea
  - visual changes
- **Serious allergic reactions.** Serious allergic reactions can happen with Effient, or if you have had a serious allergic reaction to medicines called thienopyridines, for example clopidogrel (Plavix*) or ticlopidine hydrochloride. **Get medical help right away if you get any of these symptoms of a severe allergic reaction while taking Effient.**
  - swelling or hives of your face, lips, in or around your mouth, or throat
  - trouble breathing or swallowing
  - chest pain or pressure
  - dizziness or fainting

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of Effient. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Effient?

- Keep Effient at room temperature between 59°F to 86°F (15°C to 30°C).
- Keep and dispense only in original container.
- Keep the container closed tightly with the gray cylinder inside.
- Protect Effient from moisture.

Keep Effient and all medicines out of the reach of children.

General information about the safe and effective use of Effient

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Effient for a condition for which it was not prescribed. Do not give your Effient to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about Effient. If you would like more information about Effient, talk with your doctor or pharmacist.

What are the ingredients in Effient?

Active ingredient: prasugrel

Inactive ingredients: mannitol, hypromellose, low-substituted hydroxypropyl cellulose, microcrystalline cellulose, sucrose stearate, and glyceryl behenate. The color coatings contain lactose, hypromellose, titanium dioxide, triacetin, iron oxide yellow, and iron oxide red (only in Effient 10 mg tablet).

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For more information, call 1-877-437-7763 or go to www.effient.com.

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