

## **PRASUGREL**

### **INDICATIONS:**

**For arterial thromboembolism prophylaxis (thrombotic cardiovascular events including stent thrombosis) in patients with acute coronary syndrome (i.e., unstable angina, non-ST-elevation myocardial infarction [NSTEMI], or ST-elevation acute myocardial infarction [STEMI]) who are to be managed with percutaneous coronary intervention (PCI).**

### **SAFETY ALERT:**

#### **1. Adverse Drug Reactions:**

##### **Severe**

bradycardia / Rapid / 2.9-2.9  
atrial fibrillation / Early / 2.9-2.9  
new primary malignancy / Delayed / 1.6-1.6  
GI bleeding / Delayed / 1.5-1.5  
intracranial bleeding / Delayed / 1.4-1.4  
retroperitoneal bleeding / Delayed / 0.3-0.3  
angioedema / Rapid / 0.1-0.1  
anaphylactoid reactions / Rapid / Incidence not known

##### **Moderate**

hypertension / Early / 7.5-7.5  
hypercholesterolemia / Delayed / 7.0-7.0  
hyperlipidemia / Delayed / 7.0-7.0  
dyspnea / Early / 4.9-4.9  
hypotension / Rapid / 3.9-3.9  
chest pain (unspecified) / Early / 3.1-3.1  
leukopenia / Delayed / 2.8-2.8  
peripheral edema / Delayed / 2.7-2.7  
bleeding / Early / 2.4-2.4  
anemia / Delayed / 2.2-2.2  
hemoptysis / Delayed / 0.6-0.6  
hematoma / Early / 0.5-0.5  
thrombocytopenia / Delayed / 0.3-0.3  
neutropenia / Delayed / 0-0.1

##### **Mild**

epistaxis / Delayed / 6.2-6.2  
headache / Early / 5.5-5.5  
back pain / Delayed / 5.0-5.0  
nausea / Early / 4.6-4.6  
dizziness / Early / 4.1-4.1  
cough / Delayed / 3.9-3.9  
fatigue / Early / 3.7-3.7  
rash / Early / 2.8-2.8  
fever / Early / 2.7-2.7  
diarrhea / Early / 2.3-2.3

## 2. Drug interactions:

### Warfarin

Coadministration of Effient and warfarin increases the risk of bleeding

### Non-Steroidal Anti-Inflammatory Drugs

Coadministration of Effient and NSAIDs (used chronically) may increase the risk of bleeding

### Opioids

As with other oral P2Y12 inhibitors, co-administration of opioid agonists delay and reduce the absorption of prasugrel's active metabolite presumably because of slowed gastric emptying [see [CLINICAL PHARMACOLOGY](#)]. Consider the use of a parenteral anti-platelet agent in acute coronary syndrome patients requiring co-administration of morphine or other opioid agonists.

### Other Concomitant Medications

Effient can be administered with drugs that are inducers or inhibitors of cytochrome P450 enzymes [see [CLINICAL PHARMACOLOGY](#)]. 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 H2 blockers

## 3. Contraindications and precautions

- **Anticoagulant therapy, bleeding, body weight less than 60 kg, coronary artery bypass graft surgery (CABG), GI bleeding, intracranial bleeding, peptic ulcer disease, surgery, trauma**
- **Stroke**
- **Hepatic disease**
- **Thrombotic thrombocytopenic purpura (TTP)**
- **Abrupt discontinuation.**

- **Asian patients**
- **Children**
- Safe and effective use of prasugrel have not been established in children.
- **Pregnancy**
- There are no data with the use of prasugrel in pregnant women to inform a drug-associated risk. Reproduction and toxicology studies performed in rats and rabbits at doses up to 30 to 150 times the recommended daily human dose demonstrated no evidence of impaired fertility or fetotoxicity due to prasugrel. Carefully weigh the benefits and risks of prasugrel and possible risks to the fetus when using prasugrel during pregnancy.
- **Breast-feeding**
- There is no information about the presence of prasugrel in human milk, the effects on the breastfed infant, or the effects on milk production; however, prasugrel metabolites were found in rat milk. The developmental and health benefits of breast-feeding should be considered along with the mother's clinical need for prasugrel and any potential adverse effects on the breast-fed infant from prasugrel or the mother's underlying condition.
- **Renal impairment.**
- **Thienopyridine hypersensitivity**
- **Geriatric**