



**Impairment of Fertility:** Prasugrel had no effect on fertility of male and female rats at oral doses up to 300 mg/kg/day (80 times the human major metabolite exposure at daily dose of 10 mg prasugrel).

**14. CLINICAL STUDIES**

The clinical evidence for the effectiveness of prasugrel tablets is derived from the TRITON-TIMI 38 (Clinical to Assess Improvement in Therapeutic Outcomes by Optimizing Platelet Inhibition with Prasugrel) study, a 13,508 patient, multicenter, international, randomized, double-blind, parallel-group study comparing prasugrel tablets to a regimen of clopidogrel, each added to aspirin and other standard therapy, in patients with ACS (UA, NSTEMI, or STEMI) who were to be managed with PCI. Randomization was stratified for UANSTEMI and STEMI.

Patients with UANSTEMI presenting within 72 hours of symptom onset were to be randomized after undergoing coronary angiography. Patients with STEMI presenting within 12 hours of symptom onset could be randomized prior to coronary angiography. Patients with STEMI presenting between 12 hours and 14 days of symptom onset were to be randomized after undergoing coronary angiography. Patients underwent PCI, and for both UANSTEMI and STEMI patients, the loading dose was to be administered anytime between randomization and 1 hour after the patient left the catheterization lab. If patients with STEMI were treated with thrombolytic therapy, randomization could not occur until at least 24 hours (for tenecteplase, reteplase, or alteplase) or 48 hours (for streptokinase) after the thrombolytic was given.

Patients were randomized to receive prasugrel tablets (60 mg loading dose followed by 10 mg once daily) or clopidogrel (300 mg loading dose followed by 75 mg once daily), with administration and follow-up for a minimum of 6 months (actual median 14.5 months). Patients also received aspirin (75 mg to 325 mg once daily). Other therapies, such as heparin and intravenous glycoprotein IIb/IIIa (GPIIb/IIIa) inhibitors, were administered at the discretion of the treating physician. Oral anticoagulants, other platelet inhibitors, and chronic NSAIDs were not allowed.

The primary outcome measure was the composite of cardiovascular death, nonfatal MI, or nonfatal stroke in the UANSTEMI population. Success in this group allowed analysis of the same endpoint in the overall ACS and STEMI populations. Nonfatal MI included both MI with and without Q waves. The difference in the primary outcome between prasugrel and clopidogrel was statistically significant in the UANSTEMI population. Approximately 90% of patients underwent PCI. The study drug was administered after the first coronary guideline was placed in approximately 75% of patients.

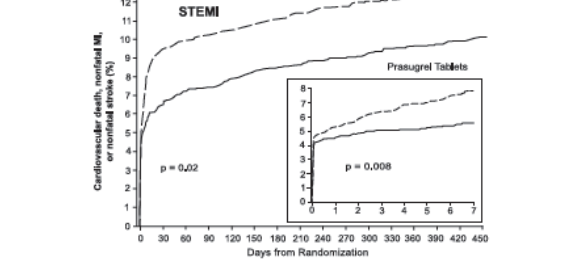
Prasugrel tablets significantly reduced total endpoint events compared to clopidogrel (see Table 5 and Figure 3). The reduction in total endpoint events was driven primarily by a decrease in nonfatal MI, both those occurring early (through 3 days) and later (after 3 days). Approximately 40% of MI occurred peri-procedure and were detected solely through analysis of creatine kinase muscle-brain (CK-MB) changes and clinically apparent (investigator-reported) MI.

The patient population was 92% Caucasian, 26% female, and 39% ≥ 65 years of age. The median time from symptom onset to study drug administration was 7 hours for patients with STEMI and 30 hours for patients with UANSTEMI. Approximately 90% of patients underwent PCI. The study drug was administered after the first coronary guideline was placed in approximately 75% of patients.

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The treatment effect of prasugrel tablets was consistent within the first few days, and persisted to the end of the study (see Figure 3). The inset shows results over the first 7 days.

**Figure 3: Time to first event of CV death, MI, or stroke (TRITON-TIMI 38)**



The Kaplan-Meier curves (see Figure 3) show the primary composite endpoint of CV death, nonfatal MI, or nonfatal stroke over time in the UANSTEMI and STEMI populations. In both populations, the curves separate within the first few hours. In the UANSTEMI population, the curves continue to diverge throughout the 15-month follow-up period. In the STEMI population, the early separation was maintained throughout the 15-month follow-up period, but there was no progressive divergence after the first few weeks.

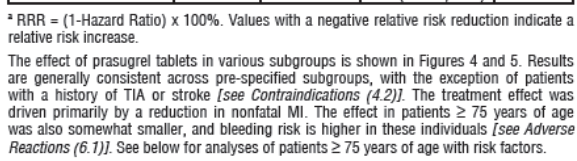
Prasugrel tablets reduced the occurrence of the primary composite endpoint compared to clopidogrel in both the UANSTEMI and STEMI populations (see Table 5). In patients who survived on-study myocardial infarction, the incidence of subsequent events was also lower in the prasugrel tablets group.

Table 5: Patients with Outcome Events (CV Death, MI, Stroke) in TRITON-TIMI 38. A table with columns for Patient Characteristics, Prasugrel Tablets (N=5844), Clopidogrel (N=5638), Relative Risk Reduction (95% CI), and p-value.

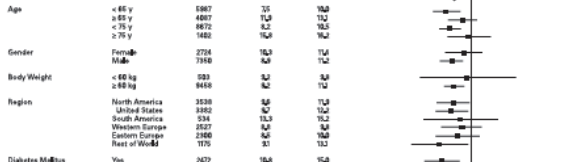
\* RRR = (1-Hazard Ratio) x 100%. Values with a negative relative risk reduction indicate a relative risk increase.

The effect of prasugrel tablets in various subgroups is shown in Figures 4 and 5. Results are generally consistent across pre-specified subgroups, with the exception of patients with a history of TIA or stroke (see Contraindications (4.2)). The treatment effect was driven primarily by a reduction in nonfatal MI. The effect in patients ≥ 75 years of age was also somewhat smaller, and bleeding risk is higher in these individuals (see Adverse Reactions (6.1)). See below for analyses of patients ≥ 75 years of age with risk factors.

**Figure 4: Subgroup analyses for time to first event of CV death, MI, or stroke (HR and 95% CI; TRITON-TIMI 38) – UANSTEMI Patients.**



**Figure 5: Subgroup analyses for time to first event of CV death, MI, or stroke (HR and 95% CI; TRITON-TIMI 38) – STEMI Patients.**



Prasugrel tablets are generally not recommended in patients ≥ 75 years of age, except in high-risk situations (diabetes mellitus or prior MI) where the effect appears to be greater and its use may be considered. These recommendations are based on subgroup analyses (see Table 6) and must be interpreted with caution, but the data suggest that prasugrel tablets are effective in these patients.

**Table 6: Subgroup Analyses for Time to First Event of CV Death, MI, or Stroke: Patients ≥ 75 Years of Age, ≥ Diabetes, or Prior History of MI, All ACS Patient Population**

Table 6: Subgroup Analyses for Time to First Event of CV Death, MI, or Stroke: Patients ≥ 75 Years of Age, ≥ Diabetes, or Prior History of MI, All ACS Patient Population. A table with columns for Patient Characteristics, Prasugrel Tablets (N, % with events), Clopidogrel (N, % with events), Hazard Ratio (95% CI).

There were 50% fewer stent thromboses (95% CI, 32% to 64%; p < 0.001) reported among patients randomized to prasugrel tablets (0.9%) than among patients randomized to clopidogrel (1.9%). The difference manifested early and was maintained throughout one year of follow-up. Findings were similar with bare metal and drug-eluting stents.

In TRITON-TIMI 38, prasugrel reduced ischemic events (major nonfatal MIs) and increased bleeding events (see Adverse Reactions (6.1)) relative to clopidogrel. The findings are consistent with the intended greater inhibition of platelet aggregation by prasugrel at the doses used in the study (see Clinical Pharmacology (12.2)). There is, however, an alternative explanation: both prasugrel and clopidogrel are pro-drugs that must be metabolized to their active moieties. Whereas the pharmacokinetics of prasugrel's active metabolite are not known to be affected by genetic variations in CYP2B6, CYP2C9, CYP2C19, or CYP3A5, the pharmacokinetics of clopidogrel's active metabolite are affected by CYP2C19 genotype, and approximately 30% of Caucasians are reduced-metabolizers. Moreover, certain proton pump inhibitors, widely used in the ACS patient population and used in TRITON-TIMI 38, inhibit CYP2C19, thereby decreasing formation of clopidogrel's active metabolite. Thus, reduced-metabolizer status and use of proton pump inhibitors may diminish clopidogrel's activity in the population, and may have contributed to prasugrel's greater treatment effect and greater bleeding risk in TRITON-TIMI 38. The extent to which these factors were operational, however, is unknown.

**16. HOW SUPPLIED/STORAGE AND HANDLING**

**16.1 How Supplied**  
Prasugrel Tablets are available containing 5.49 mg or 10.98 mg of prasugrel hydrochloride equivalent to 5 mg or 10 mg of prasugrel, respectively.

The 5 mg tablets are yellow, film-coated, capsule shaped, uncoated tablets debossed with M on one side of the tablet and PH1 on the other side. They are available as follows:

- NDC 0378-5185-93 bottles of 50 tablets
- NDC 0378-5185-77 bottles of 90 tablets (unit-of-use)
- NDC 0378-5185-05 bottles of 500 tablets

The 10 mg tablets are brown, film-coated, capsule shaped, uncoated tablets debossed with M on one side of the tablet and PH2 on the other side. They are available as follows:

- NDC 0378-5186-93 bottles of 50 tablets
- NDC 0378-5186-77 bottles of 90 tablets (unit-of-use)
- NDC 0378-5186-05 bottles of 500 tablets

**16.2 Storage and Handling**

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.] Protect from moisture.

Keep container closed and do not remove desiccant from bottle. Do not break the tablet. **Bottles of 30 tablets and bottles of 90 tablets (unit-of-use):** Dispense and keep only in original container.

**Bottles of 500 tablets:** Dispense in a light, light-resistant container as defined in the USP using a child-resistant closure.

**PHARMACIST:** Dispense a Medication Guide with each prescription.

**17. PATIENT COUNSELING INFORMATION**

See FDA-approved patient labeling (Medication Guide).

**Benefits and Risks**

- Summarize the effectiveness features and potential side effects of prasugrel tablets.
- Tell patients to take prasugrel tablets exactly as prescribed.
- Remind patients not to discontinue prasugrel tablets without first discussing it with the physician who prescribed prasugrel tablets.
- Recommend that patients read the Medication Guide.

**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.

**Other Signs and Symptoms Requiring Medical Attention**

- Inform patients that TTP is a rare but serious condition that has been reported with prasugrel tablets.
- Instruct patients to get prompt medical attention if they experience any of the following symptoms that cannot otherwise be explained: fever, weakness, extreme skin paleness, purple skin patches, yellowing of the skin or eyes, or neurological changes.
- Inform patients that they may have hypersensitivity reactions including rash, angioedema, anaphylaxis, or other manifestations. Patients who have had hypersensitivity reactions to other thienopyridines may have hypersensitivity reactions to prasugrel tablets.

**Invasive Procedures**

- Instruct patients to: inform physicians and dentists that they are taking prasugrel tablets before any invasive procedure is scheduled; tell the doctor performing the invasive procedure to talk to the prescribing health care professional before stopping prasugrel tablets.

**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).

**Medication Guide Prasugrel Tablets (pra' soo grel)**

Read this Medication Guide before you start taking prasugrel tablets and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or your treatment.

**What is the most important information I should know about prasugrel tablets?**

- Prasugrel tablets are used to lower your chance of having a heart attack or other serious problems with your heart or blood vessels. But, prasugrel tablets can cause bleeding, which can be serious, and sometimes lead to death. You should not start to take prasugrel tablets 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 prasugrel tablets and then have heart bypass surgery.

**Do not take prasugrel tablets 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 prasugrel tablets. See the end of this Medication Guide for a list of ingredients in prasugrel tablets.

**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 prasugrel tablets, your doctor will probably stop your prasugrel tablets. Follow your doctor's instructions about stopping prasugrel tablets. Do not stop taking prasugrel tablets unless your doctor tells you to.

**Before having any surgery you should talk to your doctor about stopping prasugrel tablets. If possible, prasugrel tablets should be stopped at least 1 week (7 days) before any surgery, as instructed by the doctor who prescribed prasugrel tablets for you.**

**Your risk of bleeding while taking prasugrel tablets 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 non-steroidal 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.**

- Prasugrel tablets increase your risk of bleeding because it lessens the ability of your blood to clot. While you take prasugrel tablets:

- 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 prasugrel tablets without talking to the doctor who prescribes them for you. People who are treated with angioplasty and have a stent, and stop taking prasugrel tablets too soon, have a higher risk of a blood clot in the stent, having a heart attack, or dying. If you must stop prasugrel tablets because of bleeding, your risk of a heart attack may be higher. See "What are the possible side effects of prasugrel tablets?" for more information about side effects.**

**What are prasugrel tablets?**

Prasugrel tablets are 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).

Prasugrel tablets are 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. Prasugrel tablets help prevent platelets from sticking together and forming a clot that can block an artery or a stent.

It is not known if prasugrel tablets are safe and work in children.

**What should I tell my doctor before taking prasugrel tablets?**

Prasugrel tablets may not be right for you. 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 (Ticlid)
- 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 prasugrel tablets?"

- pregnant, or are planning to get pregnant. It is not known if prasugrel tablets will harm your baby.
- if you are breastfeeding. It is not known if prasugrel passes into your breast milk. You and your doctor should decide if you will take prasugrel tablets or breastfeed. You should not do both without talking with your doctor.

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

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

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 prasugrel tablets?**

- Take prasugrel tablets exactly as prescribed by your doctor.
- Take prasugrel tablets one time each day.
- You can take prasugrel tablets with or without food.
- Take prasugrel tablets with aspirin as instructed by your doctor.

Your doctor will decide how long you should take prasugrel tablets. Do not stop taking prasugrel tablets without first talking to the doctor who prescribed it for you. See "What is the most important information I should know about prasugrel tablets?"

- If you miss a dose, take prasugrel tablets as soon as you remember. If it is almost time for your next dose, skip the missed dose. Do not take two doses at the same time.
- If you take too many prasugrel tablets, 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 prasugrel tablets?**

Prasugrel tablets can cause serious side effects, including:

- See "What is the most important information I should know about prasugrel tablets?"
- A blood clotting problem called Thrombotic Thrombocytopenic Purpura (TTP). TTP can happen with prasugrel tablets, 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 prasugrel tablets, or if you have had a serious allergic reaction to the medicine clopidogrel (Plavix) or ticlopidine (Ticlid). **Get medical help right away if you get any of these symptoms of a severe allergic reaction while taking prasugrel tablets.**

- 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 prasugrel tablets. 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 prasugrel tablets?**

- Store prasugrel tablets at room temperature at 20° to 25°C (68° to 77°F).
- Keep prasugrel tablets in the container they come in.
- Keep the container closed tightly with the desiccant inside.
- Protect prasugrel tablets from moisture.

Keep prasugrel tablets and all medicines out of the reach of children.

**General information about prasugrel tablets**  
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use prasugrel tablets for a condition for which they were not prescribed. Do not give your prasugrel tablets to other people, even if they have the same symptoms you have. They may harm them.

This Medication Guide summarizes the most important information about prasugrel tablets. If you would like more information about prasugrel tablets, talk with your doctor or pharmacist. For more information, call Mylan Pharmaceuticals Inc. at 1-877-446-3679 (1-877-4-INFO-RX).

**What are the ingredients in prasugrel tablets?**

Active ingredient: prasugrel hydrochloride

Inactive ingredients: crospovidone, glyceryl behenate, hypromellose, lactose monohydrate, mannitol, pregelatinized starch (corn), sucrose stearic acid esters, titanium dioxide, triacetin, and yellow iron oxide. The 5 mg tablets also contain FD&C Yellow No. 6 Aluminum Lake. The 10 mg tablets also contain black iron oxide and red iron oxide.

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Manufactured by: Mylan Laboratories Limited Hyderabad — 500 034, India

Code No.: MH/DH/RUGS/AD/089

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Revised: 1/2017 MXA-PRAS:R2mhm

**talk to the doctor who prescribed prasugrel tablets for you, before you have any surgery or invasive procedure.**

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

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

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- Take prasugrel tablets with aspirin as instructed by your doctor.
- Your doctor will decide how long you should take prasugrel tablets. Do not stop taking prasugrel tablets without first talking to the doctor who prescribed it for you. See "What is the most important information I should know about prasugrel tablets?"

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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.

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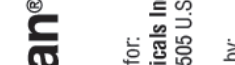
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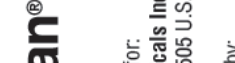
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## Medication Guide Prasugrel Tablets (pra' soo grel)

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- Do not take prasugrel tablets 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 prasugrel tablets. See the end of this Medication Guide for a list of ingredients in prasugrel tablets.
- 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 prasugrel tablets, your doctor will probably stop your prasugrel tablets. Follow your doctor's instructions about stopping prasugrel tablets. Do not stop taking prasugrel tablets unless your doctor tells you to.**
- Before having any surgery you should talk to your doctor about stopping prasugrel tablets. If possible, prasugrel tablets should be stopped at least 1 week (7 days) before any surgery, as instructed by the doctor who prescribed prasugrel tablets for you.**

### Your risk of bleeding while taking prasugrel tablets 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 non-steroidal 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.

- Prasugrel tablets increase your risk of bleeding because it lessens the ability of your blood to clot. While you take prasugrel tablets:
  - 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 prasugrel tablets without talking to the doctor who prescribes them for you. People who are treated with angioplasty and have a stent, and stop taking prasugrel tablets too soon, have a higher risk of a blood clot in the stent, having a heart attack, or dying. If you must stop prasugrel tablets because of bleeding, your risk of a heart attack may be higher. See "What are the possible side effects of prasugrel tablets?" for more information about side effects.**

### What are prasugrel tablets?

Prasugrel tablets are 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).

Prasugrel tablets are 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. Prasugrel tablets help prevent platelets from sticking together and forming a clot that can block an artery or a stent.

It is not known if prasugrel tablets are safe and work in children.

### What should I tell my doctor before taking prasugrel tablets?

Prasugrel tablets may not be right for you. 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 (Ticlid)
- 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 prasugrel tablets?"
- pregnant, or are planning to get pregnant. It is not known if prasugrel tablets will harm your baby.
- if you are breastfeeding. It is not known if prasugrel passes into your breast milk. You and your doctor should decide if you will take prasugrel tablets or breastfeed. You should not do both without talking with your doctor.

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

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

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 prasugrel tablets?

- Take prasugrel tablets exactly as prescribed by your doctor.

- Take prasugrel tablets one time each day.
- You can take prasugrel tablets with or without food.
- Take prasugrel tablets with aspirin as instructed by your doctor.
- Your doctor will decide how long you should take prasugrel tablets. Do not stop taking prasugrel tablets without first talking to the doctor who prescribed it for you. See "What is the most important information I should know about prasugrel tablets?"
- If you miss a dose, take prasugrel tablets 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 many prasugrel tablets, 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 prasugrel tablets?

Prasugrel tablets can cause serious side effects, including:

- See "What is the most important information I should know about prasugrel tablets?"**
- A blood clotting problem called Thrombotic Thrombocytopenic Purpura (TTP).** TTP can happen with prasugrel tablets, 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 prasugrel tablets, or if you have had a serious allergic reaction to the medicine clopidogrel (Plavix) or ticlopidine (Ticlid). **Get medical help right away if you get any of these symptoms of a severe allergic reaction while taking prasugrel tablets.**
  - 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 prasugrel tablets. 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 prasugrel tablets?

- Store prasugrel tablets at room temperature at 20° to 25°C (68° to 77°F).
- Keep prasugrel tablets in the container they come in.
- Keep the container closed tightly with the desiccant inside.
- Protect prasugrel tablets from moisture.

Keep prasugrel tablets and all medicines out of the reach of children.

**General information about prasugrel tablets**  
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use prasugrel tablets for a condition for which they were not prescribed. Do not give your prasugrel tablets to other people, even if they have the same symptoms you have. They may harm them.

This Medication Guide summarizes the most important information about prasugrel tablets. If you would like more information about prasugrel tablets, talk with your doctor or pharmacist. For more information, call Mylan Pharmaceuticals Inc. at 1-877-446-3679 (1-877-4-INFO-RX).

### What are the ingredients in prasugrel tablets?

Active Ingredient: prasugrel hydrochloride

Inactive Ingredients: crosopovidone, glyceryl behenate, hypromellose, lactose monohydrate, mannitol, pregelatinized starch (corn), sucrose stearic acid esters, titanium dioxide, triacetin, and yellow iron oxide. The 5 mg tablets also contain FD&C Yellow No. 6 Aluminum Lake. The 10 mg tablets also contain black iron oxide and red iron oxide.

*This Medication Guide has been approved by the U.S. Food and Drug Administration.*

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Manufactured for:  
**Mylan Pharmaceuticals Inc.**  
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