Medication Guide
Prasugrel Tablets
(pra’ soo græl)

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 internal 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. It is 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 any of your medicines 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:
  - bleeding that is severe or you cannot control
  - pink or brown urine
  - red or black stools (looks like tar)
  - bruises that happen without a known cause or get larger
  - cough up blood or blood clots
  - blood in 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 aspirin therapy and prasugrel tablets too soon, have a higher risk of a blood clot in the heart, having a heart attack, or dying. If you must stop prasugrel tablets because of bleeding, your risk of having 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 blood 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 veins, or death.
Plaques are blood cells that help with normal blood clotting. Prasugrel tablets help prevent plaques from sticking together and forming a clot that can block an artery or a vein.
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. Talk to your doctor about all of your medical conditions, including:
- have any bleeding problems
- have had a "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, color polyps, diverticulosis
- have liver problems
- have had a 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?”

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 are the possible side effects of 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.
- Your doctor will explain how your doctor or pharmacist.
- 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?”

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 1-877-466-6722 (1-877-466-6722). What are the ingredients in prasugrel tablets?
Active Ingredient: prasugrel hydrochloride
Inactive Ingredients: crospovidone, glycerol behenate, hyprocel, lactose monohydrate, mannitol, pregelatinized starch (corn), sucrose stearic acid esters, titanium dioxide, yellow iron oxide, 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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