

Medication Guide Prasugrel Tablets, USP (pra' soo grel)

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.

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.

Who should not take prasugrel tablets?

- **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 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 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.

- Prasugrel tablets increase your risk of bleeding because they lessen 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 should I tell my doctor before taking prasugrel tablets?

Before you take prasugrel tablets, 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 prasugrel tablets?**”
- are pregnant, or are planning to get pregnant. It is not known if prasugrel will harm your baby.
- 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 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 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.
- Do not split prasugrel tablets.
- 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 them 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 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 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?

- Keep prasugrel tablets at room temperature between 20° to 25°C (68° to 77°F).
- Keep and dispense only in original container.
- 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 the safe and effective use of 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.

What are the ingredients in prasugrel tablets?

Active ingredient: prasugrel

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.

The brands listed are trademarks of their respective owners.

Manufactured by: Mylan Laboratories Limited, Hyderabad – 500 096, India

Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 U.S.A.

For more information, call Mylan at 1-877-446-3679 (1-877-4-INFO-RX).

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



Manufactured for:
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