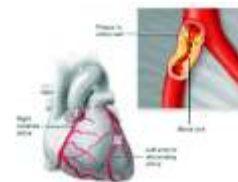
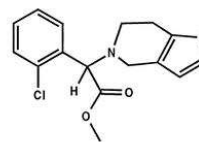


Rx CLOPIDOGREL

(Clopidogrel bisulfate is an anti-platelet drug)



GENERIC NAME: clopidogrel bisulfate

DRUG CLASS AND MECHANISM

Clopidogrel bisulfate is an anti-platelet drug, that is, a drug that inhibits the ability of platelets to clump together as part of a blood clot. It is similar to ticlopidine (Ticlid) in chemical structure and in the way it works. Unlike ticlopidine, clopidogrel bisulfate does not cause serious reductions of white cells in the blood and, therefore, routine blood testing to determine if the white blood cell count is low is not necessary during treatment.

The risk of heart attacks and strokes (which usually are caused by blood clots) is increased in patients with a recent history of stroke or heart attack and patients with peripheral vascular disease. (Peripheral vascular disease is the same as atherosclerotic arterial disease or "hardening" of the arteries in which the arteries become narrowed. It frequently occurs in the legs and often causes claudication or pain in the legs upon walking). Clopidogrel bisulfate is used to reduce the risk of heart attacks and strokes in these patients. Clopidogrel bisulfate was approved by the FDA in 1997.

GENERIC AVAILABLE: No

PRESCRIPTION: Yes

PREPARATIONS: Tablets: 75mg.

PRESCRIBED FOR

Clopidogrel is used to prevent strokes and heart attacks in persons who are at high risk. In one large study, clopidogrel bisulfate was more effective than aspirin in reducing heart attacks. The frequency of side effects of clopidogrel bisulfate was similar to aspirin; however, stomach and intestinal bleeding probably occurs less often with clopidogrel bisulfate than with aspirin.

DOSING

Clopidogrel bisulfate usually is taken once daily. It can be taken with or without food.

DRUG INTERACTIONS

The combination of clopidogrel with nonsteroidal antiinflammatory drugs (NSAIDs) such as ibuprofen (Motrin, Advil, Nuprin), naproxen (Naprosyn, Aleve), diclofenac (Voltaren), etodolac (Lodine), nabumetone (Relafen), fenoprofen (Nalfon), flurbiprofen (Ansaid), indomethacin (Indocin), ketoprofen (Orudis; Oruvail), oxaprozin (), piroxicam (Feldene), sulindac (Clinoril), tolmetin (Tolectin), and mefenamic acid (Ponstel) may increase the risk of stomach and intestinal bleeding.

At high concentrations in the blood, clopidogrel inhibits the activity of the enzyme which metabolizes (eliminates) warfarin (Coumadin), a "blood thinner". This could lead to an increase in levels of warfarin and increase the risk of bleeding due to over-thinning of the blood. To date there have been no reports of an important interaction in humans between warfarin and clopidogrel. Nonetheless, because warfarin increases the risk of bleeding, blood tests to measure the degree to which the blood is anti-coagulated or thinned (prothrombin time; INR) may be ordered to assess the degree of blood-thinning when warfarin and clopidogrel are used together. The same enzyme also is responsible for the metabolism of phenytoin (Dilantin), tamoxifen (Nolvadex), tolbutamide (Orinase), torsemide (Demadex), and fluvastatin (Lescol). Although important interactions between clopidogrel and these drugs are unlikely, interactions should be looked for carefully.

Clopidogrel is converted to its active form by enzymes in the liver. Drugs that reduce the activity of these enzymes (for example, omeprazole [Prilosec, Zegerid], esomeprazole [Nexium]) may reduce the activity of clopidogrel and should not be used with clopidogrel. Other drugs that also may react with clopidogrel in a similar fashion include fluoxetine (Prozac, Sarafem), cimetidine (Tagamet), fluconazole (Diflucan), ketoconazole (Nizoral, Extina, Xolegel, Kuric), voriconazole (Vfend), ethavrine (Ethatab, Ethavex), felbamate (Felbatol), and fluvoxamine (Luvox).

USES

Clopidogrel is used to prevent heart attacks and strokes in persons with heart disease (recent heart attack, unstable angina), recent stroke, or blood circulation disease (peripheral vascular disease). It works by blocking certain blood cells called platelets and prevents them from forming harmful blood clots. This "anti-platelet" effect helps to keep blood flowing smoothly in your body.

HOW TO USE

Take this medication by mouth usually once daily, with or without food, or as directed by your doctor. Use this medication regularly in order to get the most benefit from it. Remember to use it at the same time each day.

SIDE EFFECTS

Stomach upset/pain, diarrhea, constipation, headache, dizziness, rash, flu-like symptoms, or back/joint pain may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. While you are taking this drug, it may take longer for bleeding to stop if you experience a cut or injury. Although unlikely, tell your doctor immediately if any of these signs of serious bleeding occur: unusual or easy bruising/bleeding, black stools, vomit that looks like coffee grounds. Tell your doctor immediately if any of these unlikely but serious side effects occur: chest pain, swelling, depression. Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: signs of infection (e.g., fever, persistent sore throat), unusual weakness, vision changes, slurred speech, confusion. A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: severe rash, itching, swelling, severe dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS

Before taking clopidogrel, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: blood disorders (e.g., hemophilia), bleeding conditions (e.g., active peptic ulcers). Before using this medication, tell your doctor or pharmacist your medical history, especially of: recent surgery, serious injury (physical trauma), severe liver disease, severe kidney disease, history of abnormal bleeding, other conditions that may put you at high risk for bleeding (e.g., certain stomach/abdominal problems, certain eye diseases). Before having surgery, tell your doctor or dentist that you are taking this medication. Your doctor may instruct you to stop clopidogrel prior to surgery. This drug may make you dizzy; use caution engaging in activities requiring alertness such as driving or using machinery. Limit alcoholic beverages. Daily use of alcohol, especially when combined with this medicine, may increase your risk for stomach bleeding. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. It is not known whether this drug passes into breast milk. Breast-feeding is not recommended while using this drug. Consult your doctor before breast-feeding.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly.

MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store the US product at room temperature (77 degrees F or 25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Store the Canadian product at room temperature between 59-86 degrees F (15-30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.



Taj Group of Companies ^{INDIA}

Taj Pharmaceuticals Ltd.

Phone : General EPA BX : 91 - (0)22 - 26374592/92 91,
(0)22 - 26374592/93 91 - (0)22 - 30601000,
Fax : 91-(0)22-26341274

Revised November 2010