

PLAVIX - Abbreviated Prescribing Information

Therapeutic indication: Plavix is taken by adults to prevent blood clots (thrombi) forming in hardened blood vessel (arteries), a process known as atherothrombosis, which can lead to atherothrombotic events (such as stroke, heart attack, death). **Contraindication:** not to be taken if allergic (hypersensitive) to clopidogrel, have a medical condition that is currently causing bleeding such as a stomach ulcer or bleeding within the brain, suffer from severe liver disease. **Precautions for use:** in case of risk of bleeding such as a medical condition that puts you at risk of internal bleeding. Children and adolescents: Do not give this medicine to children because it does not work. **Drug Interaction:** Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Some other medicines may influence the use of Plavix or vice versa. You should specifically tell your doctor if you take oral anticoagulants, a non-steroidal anti-inflammatory medicine, heparin, omeprazole or esomeprazole or cimetidine, fluconazole or voriconazole, ciprofloxacin, or chloramphenicol, medicine, carbamazepine, or oxcarbazepine, medicine to treat some forms of epilepsy, ticlopidine, moclobemide, Plavix in combination with acetylsalicylic acid, a substance present in many medicines used to relieve pain and lower fever. An occasional use of acetyl-salicylic acid (no more than 1,000 mg in any 24 hours period) should generally not cause a problem, but prolonged use in other circumstances should be discussed with your doctors. Plavix may be taken with or without food. **Pregnancy and breast-feeding:** It is preferable not to take this product during pregnancy. If you are pregnant or suspect that you are pregnant, you should tell your doctor or your pharmacist before taking Plavix. **Driving and using machines:** Plavix is unlikely to affect your ability to drive or to use machines. Plavix contains lactose: If you have been told by your doctor that you have an intolerance to some sugars (e.g. lactose), contact your doctor before taking this medicine. Plavix contains hydrogenated castor oil: This may cause stomach upset or diarrhea. **Dosage & administration:** Plavix (1 tablet of 300 mg or 4 tablets of 75 mg) once at the start of treatment. Then, the recommended dose is one 75 mg tablet of Plavix per day to be taken orally with or without food, and at the same time each day. You should take Plavix for as long as your doctor continues to prescribe it. **Possible side effects:** Like all medicines, this medicine can cause side effects, although not everybody gets them. Contact your doctor immediately if you experience: fever, signs of infection or extreme tiredness, signs of liver problems such as yellowing of the skin, swelling in the mouth or skin disorders such as rashes and itching, blisters of the skin. The most common side effect reported with Plavix is bleeding. Bleeding may occur as bleeding in the stomach or bowels, bruising, hematoma (unusual bleeding or bruising under the skin), nosebleed, blood in the urine. In a small number of cases, bleeding in the eye, inside the head, the lung or the joints has also been reported. **Other side effects** include: Common side effects (may affect up to 1 in 10 people): Diarrhea, abdominal pain, indigestion, or heartburn. **Storage:** Store between 15°C-30°C. **Marketing Authorization Holder and Manufacturers:** Marketing Authorization Holder: Sanofi Clir SNC, 54, rue La Boétie - F-75008 Paris – France. Manufacturers: Sanofi Winthrop Industrie 1, rue de la Vierge, Am-barès & Lagrave, F-33565 Carbon Blanc cedex, France.

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