PLAVIX ® Abridged Prescribing Information

Forms and composition: Box of 30 film-coated tablets each containing 75 mg clopidogrel. Each film coated tablet, contains 3 mg of lactose and 3.3 mg of hydrogenated castor oil. **Therapeutic indications**: Secondary prevention of atherothrombotic events in: Adult patients suffering from myocardial infarction (from a few days until less than 35 days), ischaemic stroke (from 7 days until less than 6months) or established peripheral arterial disease. Adult patients suffering from acute coronary syndrome: Non-ST segment elevation acute coronary syndrome (unstable angina or non-Q-wave myocardial infarction), including patients undergoing a stent placement following percutaneous coronary intervention, in combination with acetylsalicylic acid (ASA). ST segment elevation acute myocardial infarction, in combination with ASA in patients undergoing percutaneous coronary intervention (including patients undergoing a stent placement) or medically treated patients eligible for thrombolytic/fibrinolytic therapy. Prevention of atherothrombotic and thromboembolic events in atrial fibrillation in adult patients with atrial fibrillation who have at least one risk factor for vascular events, are not suitable for treatment with Vitamin K antagonists (VKA) and who have a low bleeding risk, clopidogrel is indicated in combination with ASA for the prevention of atherothrombotic and thromboembolic events, including stroke. **Posology and method of administration:** Adults and elderly: Clopidogrel should be given as a single daily dose of 75 mg. In patient with non-ST segment elevation, clopidogrel should be initiated with a single 300 mg loading dose continued at 75mg once a day (with ASA 75 mg-325 mg daily). Since higher doses of ASA were associated with higher risk of bleeding a dose of ASA no higher than 100mg is recommended. The optimal duration of treatment has not been formally established. Clinical trial data support use up to 12 months and maximum benefit was seen at 3 months. For ST segment elevation acute myocardial infarction: For medically treated patients eligible for thrombolytic/fibrinolytic therapy, clopidogrel should be given as a single daily dose of 75 mg initiated with a 300-mg loading dose in combination with ASA and with or without thrombolytics. For patients over 75 years of age clopidogrel should be initiated without a loading dose. Combined therapy should be started as early as possible after symptoms start and continued for at least four weeks. The benefit of the combination of clopidogrel with ASA beyond four weeks has not been studied in this setting. When percutaneous coronary intervention (PCI) is intended: Clopidogrel should be initiated at a loading dose of 600 mg in patients undergoing primary PCI and in patients undergoing PCI more than 24 hours of receiving fibrinolytic therapy. In patients ≥ 75 years old the 600 mg LD should be administered with caution. Clopidogrel 300 mg loading dose should be given in patients undergoing PCI within 24 hours of receiving fibrinolytic therapy. Clopidogrel treatment should be continued at 75 mg once a day with ASA 75 mg – 100 mg daily. Combined therapy should be started as early as possible after symptoms start and continued up to 12 months. Special populations: Elderly patients: Non-ST segment elevation acute coronary syndrome (unstable angina or non-Q-wave myocardial infarction): A 600 mg loading dose may be considered in patients <75 years of age when percutaneous coronary intervention is intended. ST segment elevation acute myocardial infarction: For medically treated patients eligible for thrombolytic/fibrinolytic therapy: in patients over 75 years of age clopidogrel should be initiated without a loading dose. For patients undergoing primary PCI and in patients undergoing PCI more than 24 hours of receiving fibrinolytic therapy: In patients ≥ 75 years old the 600 mg LD should be administered with caution. Children and adolescents: Clopidogrel should not be used in children because of efficacy concerns. **Contra-indications**: Hypersensitivity to the drug substance or any component of the product. Severe hepatic impairment. Active pathological bleeding such as peptic ulcer and intracranial haemorrhage. **Special warnings and special precautions for use:** As with other antiplatelet agents, clopidogrel should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery or other pathological conditions. If a patient is to undergo elective surgery and an antiplatelet effect is not desired, clopidogrel should be discontinued 7 days prior to surgery. Clopidogrel prolongs bleeding time and should be used with caution in patients who have lesions with a propensity to bleed (particularly gastrointestinal and intraocular). Patients should be told that it may take longer than usual to stop bleeding when they take clopidogrel, and that they should report any unusual bleeding to their physician. Patients should inform physicians and dentists that they are taking clopidogrel before any surgery is scheduled and before any new drug is taken. Due to the limited clinical data in patients ≥75 years old with STEMI PCI, and increased risk of bleeding, the use of clopidogrel 600 mg loading dose should be considered only after an individual assessment of the bleeding risk of the patient by the physician. Thrombotic Thrombocytopenic Purpura (TTP) has been reported very rarely following the use of clopidogrel, sometimes after a short exposure. It is characterised by thrombocytopenia and microangiopathic haemolytic anaemia associated with neurological findings, renal dysfunction or fever. TTP is a condition requiring prompt treatment. In patients who are poor CYP2C19 metabolisers, clopidogrel at recommended doses forms less of the active metabolite of clopidogrel and has a smaller effect on platelet function. Since clopidogrel is metabolized to its active metabolite partly by CYP2C19, use of medicinal products that inhibit the activity of this enzyme would be expected to result in reduce drug level of the active metabolite of clopidogrel. As a precaution, concomitant use of strong or moderate CYP2C19 inhibitors should be discouraged. Therapeutic experience with clopidogrel is limited in patients with renal impairment and in patients with severe hepatic disease who may have bleeding diatheses. Clopidogrel should therefore be used with caution in these populations. *Acquired haemophilia* has been reported following use of clopidogrel. In cases of confirmed isolated Partial Thromboplastin Time (aPTT) prolongation with or without bleeding, acquired haemophilia should be considered, Patients with a confirmed diagnosis of acquired haemophilia should be managed and treated by specialists, and clopidogrel should be discontinued. *Recent ischemic stroke. Non-minor IS patients. Recent minor IS or moderate to high-risk TIA in patients for whom intervention is indicated or planned.* **Interaction with other medicinal products and other forms of interaction:** *Medicinal products associated with bleeding risk: There is an increased risk of bleeding due to the potential additive effect. The concomitant administration of medicinal products associated with bleeding risk should be undertaken with caution: Oral anticoagulants, Glycoprotein IIb/IIIa inhibitors, Acetylsalicylic acid (ASA), Heparin, Thrombolytics, NSAIDs, and SSRIs.* **Use during pregnancy and lactation:** *Pregnancy:* As no clinical data on exposure to clopidogrel during pregnancy are available, it is preferable not to use clopidogrel during pregnancy as a precautionary measure. *Breast-feeding:* It is unknown whether clopidogrel is excreted in human breast milk. Animal studies have shown excretion of clopidogrel in breast milk. As a precautionary measure, breast-feeding should not be continued during treatment with Plavix. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. **Undesirable effects:** The Common Adverse reactions: *In blood and lymphatic system disorders*: Thrombocytopenia, leucopenia, eosinophilia. *In nervous system disorders*: Intracranial bleeding (some cases were reported with fatal outcome), headache, paraesthesia, dizziness. *In eye disorders*: eye bleeding (conjunctival, ocular, retinal). *Vascular disorders:* Haematoma, *Respiratory, thoracic and mediastinal disorders:* Epistaxis. *Gastrointestinal disorders:* Gastrointestinal haemorrhage, diarrhoea, abdominal Pain, dyspepsia, gastric ulcer and duodenal ulcer, gastritis, vomiting, nausea, constipation, flatulence. *Skin and subcutaneous tissue disorders:* bruising, rash, pruritus, skin bleeding (purpura). *Renal and urinary disorders:* Haematuria. *General disorders and administration site conditions:* Bleeding at puncture site. *Investigations:* Bleeding time prolonged, neutrophil count decreased, and platelet count decreased. **Overdose**: No antidote to the pharmacological activity of clopidogrel has been found. If prompt correction of prolonged bleeding time is required, platelet transfusion may reverse the effects of clopidogrel. **Shelf-life**: 3 years. Marketing Authorisation Holder. Sanofi Winthrop Industrie, 82 avenue Raspail, 94250 Gentilly, France. Revision date: 12/2022.

To report an adverse event or if you have any medical enquiry, please call +964 751 740 2599 or email us at:

Levant.Pharmacovigilance@sanofi.com **for adverse events**

Levant.medinfo@sanofi.com **for medical enquiries**

Quality.Levant@sanofi.com **for product technical complaints**

Always refer to the full Summary of Product Characteristics (SmPC) before prescribing.

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