

## Summary of prescribing information for PREVA tablets

**Active Ingredient:** Each film coated tab of PREVA contains; clopidogrel bisulphate eq.to clopidogrel-75 mg.  
**Indication:** for treatment of atherosclerosis events (myocardial infarction, stroke & vascular death); acute coronary syndrome. **Dosage:** Acute coronary syndrome: Initiate clopidogrel with a single 300 mg oral loading dose and then continue at 75 mg once daily. Initiating clopidogrel without a loading dose will delay establishment of an antiplatelet effect by several days. Recent MI, recent stroke, or established peripheral arterial disease: 75 mg once daily orally without a loading dose. **Contraindications:** Active pathological bleeding, such as peptic ulcer or intracranial Hemorrhage. Hypersensitivity to clopidogrel or any component of the product. **Warning and precautions:** CYP2C19 inhibitors: Avoid concomitant use of omeprazole or esomeprazole. Bleeding: clopidogrel increases risk of bleeding. Discontinuation: Premature discontinuation increases risk of cardiovascular events. Discontinue 5 days prior to elective surgery that has a major risk of bleeding. Thrombotic thrombocytopenic purpura (TTP) has been reported. Cross-reactivity among thienopyridines has been reported. **Pregnancy & Lactation:** Available data with clopidogrel use in pregnant women have not identified any drug-associated risks for major birth defects or miscarriage. **Interaction:** Opioids: Decreased exposure to clopidogrel. Consider use of parenteral antiplatelet agent. Nonsteroidal anti-inflammatory drugs (NSAIDs), warfarin, selective serotonin and serotonin norepinephrine reuptake inhibitors (SSRIs, SNRIs): Increases risk of bleeding. Repaglinide (CYP2C8 substrates): Increases substrate plasma concentrations. **Adverse reactions:** most common bleeding, including life-threatening and fatal bleeding. **Overdose:** Platelet inhibition by clopidogrel is irreversible and will last for the life of the platelet. Overdose following clopidogrel administration may result in bleeding complications. Symptoms of acute toxicity were vomiting, prostration, difficult breathing, and gastrointestinal hemorrhage in animals. Based on biological plausibility, platelet transfusion may restore clotting ability.

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It is recommended to refer full prescribing information before prescription.

For further medical information, please write to: Intas Pharmaceuticals Ltd., Corporate House, Near Sola Bridge, SG highway, Thaltej, Ahmedabad-380054, Gujarat, India. [productqueries@intaspharma.com](mailto:productqueries@intaspharma.com)