Summary of prescribing information for PREVA GOLD tablets

Active Ingredient: Each tablet of PREVA GOLD 10 contains; rosuvastatin calcium 10 mg, clopidogrel bisulphate eq.to clopidogrel-75 mg + aspirin IP (as enteric coated tablets) 75 mg; Each capsule of PREVA GOLD 20 contains; rosuvastatin calcium 20 mg, clopidogrel bisulphate eq.to clopidogrel-75 mg + aspirin IP (as enteric coated tablets) 75 mg. **Indication:** For the treatment of angina, myocardial infarction and stroke with dyslipidemia. **Dosage:** Adults: 1 tablet/capsule of PREVA GOLD should be taken once daily; can be taken with or without food. **Contraindications:** Active liver disease, Women who are pregnant or may become pregnant, Nursing mothers. Active pathological bleeding, such as peptic ulcer or intracranial Hemorrhage. Hypersensitivity to rosuvastatin, clopidogrel, aspirin or any NSAIDs, or component of the product. Active peptic ulceration or history of peptic ulceration; Haemophilia, other coagulopathies including hypoprothrombinaemia or concurrent anticoagulant therapy; Aspirin should not be used in children or teenagers for viral infections, with or without fever, because of the risk of Reye's syndrome. **Warning and precautions:** Rosuvastatin: Skeletal muscle effects (e.g., myopathy and rhabdomyolysis); Risks increase with use of 40 mg dose, advanced age (≥65), hypothyroidism, renal impairment, and combination use with cyclosporine, lopinavir/ritonavir, atazanavir/ritonavir, or certain other lipid-lowering drugs. Liver enzyme abnormalities and monitoring. *Clopidogrel:* 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. *Aspirin:* Coagulation abnormalities: Even low doses of aspirin can lead to an increase in bleeding time. GI Side effects: like stomach pain, heartburn, nausea, vomiting and gross GI bleeding. Peptic Ulcer Disease: cause gastric mucosal irritation and bleeding. **Pregnancy & Lactation:** contraindicated, as mentioned above. **Interaction:** *rosuvastatin:* Cyclosporine: Combination increases rosuvastatin exposure. Gemfibrozil: Combination should be avoided. If used together, limit rosuvastatin dose to 10 mg once daily. Lopinavir/Ritonavir or atazanavir/ritonavir: Combination increases rosuvastatin exposure. Coumarin anticoagulants: Combination prolongs INR. Concomitant lipid-lowering therapies: may increase the risk of skeletal muscle effects. *Clopidogrel:* 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. Aspirin: *Aspirin:* Co-administration with anticoagulants, antiplatelets, or NSAIDs can increase risk of bleeding. Decreased renal function can occur with co-administration with NSAIDs. **Adverse reactions:** rosuvastatin: Most frequent headache, myalgia, abdominal pain, asthenia, and nausea. *clopidogrel:* most common bleeding, including life-threatening and fatal bleeding. *Aspirin:* common Dyspepsia, GI bleeding, ulceration and perforation, nausea, vomiting, transient elevations of hepatic enzymes, hepatitis, Reye's syndrome, pancreatitis, prolongation of the prothrombin time, disseminated intravascular coagulation, coagulopathy, thrombocytopenia. **Overdose:** *rosuvastatin:* There is no specific treatment in the event of overdose. In the event of overdose, the patient should be treated symptomatically and supportive measures instituted as required. Hemodialysis does not significantly enhance clearance of rosuvastatin. *Clopidogrel:* 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. *Aspirin:* Salicylate toxicity may result from acute ingestion (overdose) or chronic intoxication. The early signs of salicylic overdose (salicylism), including tinnitus (ringing in the ears), occur at plasma concentrations approaching 200 mcg/ml. Plasma concentrations of aspirin above 300 mcg/ml are clearly toxic. Severe toxic effects are associated with levels above 400 mcg/ml. A single lethal dose of aspirin in adults in not known with certainty but death may be expected at 30g. In acute overdose, severe acid-base and electrolyte disturbances may occur and are complicated by hyperthermia and dehydration. Respiratory alkalosis occurs early while hyperventilation is present, but is quickly followed by metabolic acidosis. For real or suspected overdose, nearest emergency centre should be contacted immediately. Careful medical management is essential.

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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