Summary of prescribing information for PREVA RS tablets

Active Ingredient: Each capsule of PREVA RS contains; clopidogrel bisulphate eq.to clopidogrel-75 mg (as pellets) + rosuvastatin calcium 10 mg (as pellets). **Indication:** for the secondary prophylaxis of ischemic stroke with comorbid dyslipidemia. **Dosage:** Adults: one capsule should be taken once daily. The capsule should be swallowed whole. **Contraindications:** Active pathological bleeding, such as peptic ulcer or intracranial Hemorrhage. Hypersensitivity to clopidogrel, rosuvastatin, or component of the product. Active liver disease, Women who are pregnant or may become pregnant, Nursing mothers. **Warning and precautions:** *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. *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. **Pregnancy & Lactation:** contraindicated, as mentioned above. **Interaction:** *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. *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. **Adverse reactions:** *clopidogrel:* most common bleeding, including life-threatening and fatal bleeding. rosuvastatin: Most frequent headache, myalgia, abdominal pain, asthenia, and nausea. **Overdose:** *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. *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.

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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