Summary of prescribing information for PREVA AS tablets

Active Ingredient: Each film coated tab of PREVA AS contains; clopidogrel bisulphate eq.to clopidogrel-75 mg + aspirin IP (as enteric coated tablets) 75 mg/ 150 mg. **Indication:** For the treatment of angina, myocardial infarction and stroke. **Dosage:** The combination of clopidogrel & aspirin should be administered once daily. **Contraindications:** Active pathological bleeding, such as peptic ulcer or intracranial Hemorrhage. Hypersensitivity to 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:** *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:** Available data with clopidogrel and aspirin use in pregnant women have not identified any drug-associated risks for major birth defects or miscarriage. There are no data on the presence of clopidogrel in human milk or the effects on milk production. No adverse effects on breastfed infants. Based on data in breastfeeding women taking low-dose aspirin, and metabolite salicylic acid, is present in human milk in low levels. There is no information on the effects of aspirin on the breastfed infant or on milk production. **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. 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:** *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:** 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 30 g. 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