Summary of prescribing information for COLTRO AS tablets

Active Ingredient: each hard gelatin capsules of COLTRO AS contains: rosuvastatin calcium (As granules) + aspirin (As Gastro-resistant tablet IP) 10 mg +75 mg; 10 mg +150mg. **Indication:** For the treatment of dyslipidemia associated with artherssclerotic arterial disease with risk of Myocardial infarction, stroke or peripheral vascular disease. **Dosage:** This combination should be taken orally once a day or as directed by Physician. **Contraindications:** Hypersensitivity to rosuvastatin, aspirin or any other NSAIDs, or any of the excipients; 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; Patients with active liver disease, which may include unexplained persistent elevations of hepatic transaminase levels; Women who are pregnant or may become pregnant; Nursing mothers. **Warning and precautions:** 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. Advise patients to promptly report unexplained muscle pain, tenderness, or weakness and discontinue rosuvastatin if signs or symptoms appear. Liver enzyme abnormalities and monitoring: Persistent elevations in hepatic transaminases can occur. Monitor liver enzymes before and during treatment. 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:** as mentioned above. **Interaction:** *rosuvastatin:* Cyclosporine: Combination increases rosuvastatin exposure. Limit rosuvastatin dose to 5 mg once daily. 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. Limit rosuvastatin dose to 10 mg once daily. Coumarin anticoagulants: Combination prolongs INR. Achieve stable INR prior to starting rosuvastation. Monitor INR frequently until stable upon initiation or alteration of rosuvastatin therapy. Concomitant lipid-lowering therapies: Use with fibrates and niacin products may increase the risk of skeletal muscle effects. *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. *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. *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.

Prepared on 24th Feb 2020.

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