Summary of prescribing information for ARRENO tablets

Active Ingredient: Each hard gelatin capsule of ARRENO contains; aspirin IP-25mg, Dipyridamole BP-200mg (extended-release). **Indication:** For reduction of risk of stroke in patients who had transient ischemia of the brain of complete ischemic stroke due to thrombosis. **Dosage:** 1 capsule twice daily (morning and evening) with or without food. In case of intolerable headaches during initial treatment, switch to 1 capsule at bedtime and low-dose aspirin in the morning; resume BID dosing within one week. **Contraindications:** Hypersensitivity to any product ingredients, Patients with known allergy to NSAIDs, Patients with the syndrome of asthma, rhinitis, and nasal polyps. **Warning and precautions:** increases the risk of bleeding. Avoid use in patients with severe hepatic or renal insufficiency. Interrupt therapy capsules 48 hours before using intravenous dipyridamole or other adenosinergic agents for stress testing. **Pregnancy & Lactation:** Available data for use during pregnancy have not identified a clear association between drug use and major birth defects, miscarriage, or adverse maternal or fetal outcomes. Based on data in breastfeeding women taking low-dose aspirin, the metabolite salicylic acid, and dipyridamole is present in human milk in low levels. There is no information on the effects of aspirin or dipyridamole on the breastfed infant or on milk production. **Interaction:** Co-administration with anticoagulants, antiplatelets, or NSAIDs can increase risk of bleeding. Decreased renal function can occur with co-administration with NSAIDs. **Adverse reactions:** most frequently reported, headache, dyspepsia, abdominal pain, nausea, and diarrhea. **Overdose:** symptoms of dipyridamole: warm feeling, flushes, sweating, restlessness, feeling of weakness, and dizziness. A drop in blood pressure and tachycardia might also be observed. Aspirin: early signs of salicylic overdose (salicylism), including tinnitus (ringing in the ears), occur at plasma concentrations approaching 200 mcg/mL. In severe cases, hyperthermia and hypovolemia are the major immediate threats to life. Plasma concentrations of aspirin above 300 mcg/mL are clearly toxic. Severe toxic effects are associated with levels above 400 mcg/mL. Single lethal dose of aspirin in adults is not known with certainty but death may be expected at 30 g. Treatment: consists primarily of supporting vital functions, increasing drug elimination, and correcting acid-base disturbances. Consider gastric emptying and/or lavage as soon as possible after ingestion, even if the patient has vomited spontaneously. After lavage and/or emesis, administration of activated charcoal as a slurry may be beneficial if less than 3 hours have passed since ingestion. Charcoal absorption should not be employed prior to emesis and lavage. Follow acid-base status closely with serial blood gas and serum pH measurements. Maintain fluid and electrolyte balance. Administer replacement fluid intravenously and augment with correction of acidosis. Treatment may require the use of a vasopressor. Infusion of glucose may be required to control hypoglycemia. Administration of xanthine derivatives (e.g., aminophylline) may reverse the vasodilatory effects of dipyridamole overdose. Plasma electrolytes and pH should be monitored serially to promote alkaline diuresis of salicylate if renal function is normal. In patients with renal insufficiency or in cases of life-threatening intoxication, dialysis is usually required to treat salicylic overdose; however, since dipyridamole is highly protein bound, dialysis is not likely to remove dipyridamole. Exchange transfusion may be indicated in infants and young children.

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It is recommended to refer full prescribing information before prescription.

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