

Title: (don't enter authors names here)	Consistent efficacy and tolerability across 4 migraine attacks of a fixed single-tablet formulation of sumatriptan 85mg RT Technology™ and naproxen sodium 500mg (SumaRT/Nap)
Abstract:	<p>METHODS:Two identical randomized, multi-center, double-blind, placebo-controlled, multiple-attack, early intervention (treating mild within one hour), cross-over trials of adult migraineurs (ICHD-II) were conducted. Subjects were randomized to one of five sequence groups and instructed to treat four migraine attacks. Patients in four groups received SumaRT/Nap in three of four attacks and placebo (PBO) in the remaining attack. Patients in the fifth group received SumaRT/Nap for all four attacks. The primary analyses used repeated measures techniques (GEE) across attacks for both pain severity at 2 hours and sustained to 24 hours (co-primaries).</p> <p>RESULTS:In Study 1 (S1), 570 patients treated 1693 attacks with SumaRT/Nap and 424 attacks with PBO. For study 2 (S2), 565 patients treated 1678 attacks with SumaRT/Nap and 422 attacks with PBO. In S1, the overall percentage of patients who were pain free at 2hr was 52% and 25% (therapeutic gain (TG)=28%;p<0.001) for SumaRT/Nap and PBO, respectively. In S2, the overall 2hr pain free rate was 50% and 20% (TG=30%;p<0.001) for SumaRT/Nap and PBO, respectively. The percentage of patients with sustained pain freedom for SumaRT/Nap and PBO was 37% and 17% (TG=20%;p<0.001) and 34% and 12% (TG=22%;p<0.001) for S1 and S2, respectively. Adverse events were generally mild with the most common being dry mouth, nausea, and dizziness across all attacks treated in both studies.</p> <p>CONCLUSIONS:SumaRT/Nap was significantly more efficacious than PBO and was well tolerated across 4 migraine attacks.</p>