

Title: (don't enter authors names here)	Optimizing efficacy in the acute treatment of migraine: evaluation of the clinical benefits of treatment paradigm and combination therapy (fixed single-tablet formulation of sumatriptan 85mg RT Technology™ and naproxen sodium 500mg, SumaRT/Nap)
Abstract:	<p>BACKGROUND: Treatment paradigms have been studied with various triptans. The definition of “late” treatment is standardized by regulatory authorities; however, definitions of “early” treatment have varied. Co-prescription of triptans and NSAIDs is common, although, this combination has only recently been evaluated as a fixed-single-tablet formulation, SumaRT/Nap.</p> <p>OBJECTIVE: To evaluate two treatment paradigms with SumaRT/Nap.</p> <p>METHODS: Two studies each were conducted in identical randomized, multi-center, double-blind, placebo-controlled, early (EI) and late intervention (LI). EI studies randomized (1:1) subjects to placebo (PBO) or SumaRT/Nap. LI studies randomized (1:1) subjects to PBO, SumaRT, naproxen sodium or SumaRT/Nap. Sustained pain free (SPF; 2-24h) was compared using therapeutic gain (TG; active – placebo) between EI and LI and in LI, SumaRT/Nap to SumaRT.</p> <p>RESULTS: In EI, 45% and 40% of subjects treated with SumaRT/Nap had a SPF response versus 12% and 14% treated with PBO (TGs: 33, 26, resp). In LI, 23% and 25% of subjects treated with SumaRT/Nap had a SPF response versus 7% and 8% treated with PBO (TGs: 16, 17, resp). Subjects treated with SumaRT monotherapy had a SPF response in 14% and 18% of subjects (TGs: 7, 10, resp). SumaRT/Nap was well-tolerated in all 4 studies.</p> <p>CONCLUSIONS: Subjects who treated their migraine “early” were more likely to obtain sustained pain free response compared to “late” intervention. And, subjects who treated their migraine with combination therapy (SumaRT/Nap) were more likely to obtain a sustained pain free response compared to monotherapy (SumaRT). To optimize efficacy, patients should treat their migraine early with combination therapy.</p>