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| <b>Title:</b><br>(don't enter authors names here) | Early sumatriptan pharmacokinetics following a sumatriptan 100mg RT Technology™ tablet and a fixed single-tablet formulation of sumatriptan 85mg RT Technology™ and 500mg naproxen sodium.   |
| <b>Abstract:</b>                                  | <p><b>Background:</b> Migraineurs cite speed of action as an important attribute of acute migraine therapy. RT Technology™ enhances tablet disintegration, allowing medication to be absorbed and potentially reach its site of action more rapidly. A direct comparison of sumatriptan bioavailability following administration of a Fixed Single-Tablet Formulation of Sumatriptan 85mg RT Technology™ with 500mg Naproxen Sodium (SumaRT/Nap) and a Sumatriptan 100mg RT Technology™ Tablet (SumaRT) was conducted to compare acute exposures [AUC(0-2)] and peak concentrations (Cmax).</p> <p><b>Objective:</b> Evaluate and compare sumatriptan pharmacokinetics during the first 2 hours following single oral doses of SumaRT and SumaRT/Nap.</p> <p><b>Methods:</b> This was a single-center, randomized, open-label, 2-way crossover study in healthy volunteers (n=32). Adult volunteers received single doses of SumaRT and SumaRT/Nap. Serial blood samples were analyzed for sumatriptan concentrations.</p> <p><b>Results:</b> Following administration of SumaRT/Nap, sumatriptan peak concentration and acute exposure were similar, relative to SumaRT. While sumatriptan Cmax and AUC(0-2) were decreased, on average, by 10% and 4%, respectively, for SumaRT/Nap relative to SumaRT, 90% confidence intervals were within the 0.80 – 1.25 limits used to establish bioequivalence. On average sumatriptan Cmax occurred 53 minutes earlier for SumaRT/Nap compared to SumaRT.</p> <p><b>Conclusion:</b> There were no significant differences between SumaRT and SumaRT/Nap with respect to sumatriptan peak concentration and early exposure. However, the median tmax for sumatriptan occurred earlier following SumaRT/Nap compared to SumaRT.</p> |