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# Interchangeability of two oral perampanel formulations: A randomized, open label, single-dose, 2-way crossover study in healthy volunteers

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**Background & Aim:** Perampanel is a glutamate non-competitive receptor antagonist that is effective as adjunctive treatment for epilepsy. No studies regarding comparative bioavailability between a generic perampanel formulation and the brand-name product have been published in the literature. The goal of the present investigation was to compare the bioavailability and to evaluate the bioequivalence between a novel pharmaceutical equivalent 12 mg film-coated tablet formulation and the reference product.

**Methods:** An open label, randomized-sequence, two-period, two-treatment, single-dose, crossover design study in healthy volunteers (n=24) was conducted. The treatment was split out by a 42 days wash-out period. The informed consent was signed by all volunteers. Healthy subjects of both genders, including non-pregnant and non-lactating females between 21-55 years with Quetelet index between 19-29 kg/m$^2$ were enrolled. Blood samples were withdrawn in vacutainers with EDTA over 168 h and plasma levels of perampanel were measured by HPLC/fluorescence method. Pharmacokinetic variables ($C_{max}$, $AUC_{0\text{-}last}$, and $AUC_{inf}$) after a single oral administration dose of the test and reference treatments were analyzed by a non-compartmental PK model using natural log transformed data and were compared by ANOVA for a two-treatment crossover design. Bioequivalence between the two formulations was evaluated using the 90% Confidence Interval (CI) comprised between 80-125% corresponding to the ratio of the geometric means for log-transformed PK parameters.

**Results:** A similar bioavailability between products was determined. Test and reference formulations showed no statistically significant differences in relation to the fixed effect of period, sequence, treatment and volunteers within sequence as random effect for PK variables. The estimated point and 90% CI of the ratios of $C_{max}$, $AUC_{0\text{-}last}$ and $AUC_{inf}$ were 0.92 (0.83-1.03), 1.04 (0.98-1.10) and 0.98 (0.86-1.11), respectively. The formulations showed comparable safety/tolerability.

**Conclusion:** The new pharmaceutical equivalent perampanel 12 mg film-coated tablet formulation was also bioequivalent to the reference product. Therefore, both drugs are interchangeable.

## Biography

Maligne Guillermo E is the Chief of Clinical Research and BA/BE Management at Gador S.A., Buenos Aires, Argentina. He has over 12 years of experience working in the pharmaceutical industry, 17 years in medical development as Physician, 4 years in basic research project CONICET Fellowship (National Scientific Council), 8 years of experience advising oncologist clinical trials in early and late phases for clinical research.

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