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Food does not Affect the Bioavailability of Udenafil

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Background/Aims: Udenafil is a cGMP-specific phosphodiesterase type 5 inhibitor developed for the treatment of erectile dysfunction. We evaluated the effect of food on the pharmacokinetics of udenafil.

Methods: This study was conducted in an open, randomized, three-way crossover design. Fifteen healthy male volunteers received a single dose of 200 mg of udenafil orally under fasting conditions, with a low-fat meal, and with a high-fat meal separated by 7-day washout period. Serial blood samples were taken just before and after oral administration for 48 hours. Udenafil plasma concentrations were analyzed by LC-MS/MS and its pharmacokinetics were determined by noncompartmental methods.

Results: Under fasting conditions, tmax was typically observed 1 hour after administration. The median tmax values after a low-fat meal and a high fat meal were 3 hours and 2 hours, respectively. The Cmax values were 702.9 +/− 282.7 ug/L under fasting, 560.5 +/− 215.1 ug/L after a low-fat meal, and 687.5 +/− 172.2 ug/L after a high-fat meal. The AUCinf values were 5,368.2 +/− 1,908.9 ug*h/L under fasting, 5,174.7 +/− 1,643.3 ug*h/L after a low-fat meal, and 5,428.7 +/− 1,445.9 ug*h/L after a high-fat meal. The ratios (90% confidence intervals) of geometric means to fasting condition for Cmax and AUCinf were 0.79 (0.70~0.90), 0.96 (0.89~1.04) in the low-fat fed state and 1.01 (0.89~1.15), 1.03 (0.96~1.11) in the high-fat fed state.

Conclusions: The apparent tmax of udenafil was increased under fed conditions. Although Cmax was reduced by approximately 20% in the low-fat fed state, the bioavailability was not affected when taken with food.