

## Comparison Study of Novel Pde-5 Inhibitor, Udenafil, Disposition Between Healthy Elderly and Young Adult Male Subjects

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**Background/Aims:** Udenafil is a novel cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 inhibitor (PDE5I) that is currently available in South Korea for the treatment of erectile dysfunction(ED). In the prior clinical trials, udenafil was generally well tolerated and showed the efficacy of erectile dysfunction and frequency of adverse events comparable to other PDE5Is. This study was to evaluate the effect of age on the pharmacokinetics, tolerability and safety of udenafil.

**Methods:** A open, parallel, single oral dose study were conducted in healthy elderly and young adult male subjects after a single oral dose of 100mg of udenafil administration. Pharmacokinetic parameters, safety and tolerability of udenafil were compared between 12 healthy young male subjects (mean age 23 years; range 21~27 years) and 12 healthy elderly male subjects (mean age 69 years; range 65~78 years). Blood and urine samples were collected up to 60 h after dose. The assays of udenafil and its main metabolite, DA-8164, were conducted using LC/MS/MS and pharmacokinetic parameters were estimated with WinNonlin. Analysis of variance (anova) was used to compare udenafil and DA-8164 AUC and Cmax (natural log transformed), and Tmax in the young vs the elderly groups.

**Results:** The Cmax of udenafil and its metabolite, DA-8164 in elderly (214.0±100.3ng/ml, 124.4±40.8ng/ml) seems likely to be lower than that in young (292.8±96.6ng/ml, 164.6±55.4ng/ml), while t1/2 were prolonged in elderly when compared with young (16.6±3.2h vs 11.6±1.6h). Finally, no significant difference in AUCinf was observed between the elderly(1858.8±694.6ng\*hr/ml and 1768.0±634.7ng\*hr/ml) and the young subjects (2100.6±419.8ng\*hr/ml and 2072.2±652.4ng\*hr/ml) for both udenafil and its metabolite. While, all adverse events(1 migraine and 3 hot flushing) were reported only in elderly and were mild.

**Conclusion:** Oral disposition of udenafil in elderly was not different significantly when compared with that in young, in contrast to other PDE5Is. However, vascular adverse events were reported only in elderly group. This information would be useful for dosage regimen of udenafil in elderly group.