

Pharmacokinetics, safety and local tolerability of diethylstilbestrol orally dissolving film in comparison with DES-capsules in healthy male subjects

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DES Orally Dissolving Film (DES ODF) is designed to bypass the first-pass liver metabolism. The aims were to compare the pharmacokinetic profiles of DES ODF and DES-capsule form after a single-dose administration in male healthy subjects and to assess the safety, local tolerability, taste and disintegration time of the DES ODF. In a randomized, open-label, 2-way crossover trial, healthy volunteers received 2.0 mg DES ODF and capsule form and each in a single administration. Blood samples for pharmacokinetic analysis of the diethylstilbestrol was obtained during a 14-hour period after dosing. Taste, time to dissolution, and tolerability of DES ODF and capsule were assessed at approximately 5 minutes after dosing. Safety assessments included adverse events, hematology and biochemistry tests of the sampled blood, urinalysis, blood pressure measurements, and electrocardiography. The bioequivalence assessment was based on pharmacokinetic and statistical analysis of data from 12 subjects who completed both treatment periods. The plasma concentration-time profiles of the DES was not similar after intake of the two formulations. The 90% CIs for the mean treatment ratios of the log-transformed C_{max} , AUC_{0-12} , $AUC_{0-\infty}$ were 2(145-265), 1.29(99-150) and 1.6(120-200) respectively. They were all higher at ODF form than those at capsule form. The disintegration time of the ODF is 14 ± 5 minutes. Everyone can tolerate the ODF and feel very nice/pleasant. No clinically relevant changes were observed in physical, biochemical, hematologic, or urinalysis variables during the study. The DES ODF formulations appeared to be well tolerated and absorbed resulted from lacking hepatoenteral circulation.

Biography

Hong zhang has completed his medical doctor degree at the age of 30 years from the first hospital of Jilin University. He is good at Clinical pharmacology and Analysis of drug metabolism data. He has published more than 6 SCI papers in reputed journals and has been serving as an editorial board member of repute.

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