

Pharmacokinetics of 2 mg Dienogest (Visanne™) after Single and Multiple Oral Administrations in Young Healthy Chinese Women

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Introduction: Administration of 2 mg Dienogest (DNG) once daily is an approved treatment of endometriosis in many countries. To support drug registration of Visanne™ in China, this combined single/multiple dose study was conducted to assess the pharmacokinetic (PK) characteristics of DNG in Chinese healthy young women.

Materials and methods: This study was conducted as a single-centre, open-label, single arm, phase I study. Hospitalised healthy Chinese young women were given 2 mg DNG as single oral dose followed by once daily multiple oral administrations over 14 days after a 5-day washout period. The single-dose administration and the final dose of the multiple administrations were each followed by blood sampling over 60 hours. Incidences of any adverse events (AEs) were monitored throughout the study.

Results: 16 women with a mean age of 34.1 years and a mean body weight of 54.0 were treated. After oral administration, DNG was rapidly absorbed and reached mean maximum concentration of 60.0 µg/L and 64.6 µg/L at about 1.25 hour after single and repeated dosing, respectively. The mean terminal half-life was around 11 hours after single and repeated administration. Steady state was reached after 3 days of once-daily administration with a mean trough concentration value (trough level) of 10.4 µg/L. Only minor accumulation of DNG was observed after repeated oral dosing. DNG had a low inter individual variability in systemic exposure in Chinese women. The steady state PK was predictable from single dose PK indicating that the PK of DNG is time-independent. The study treatment was well tolerated by all subjects. There were no serious nor significant adverse events observed during this study.

Conclusions: After single and multiple administrations of 2 mg DNG in healthy Chinese women, the pharmacokinetics of DNG could be well described. DNG appeared to be well tolerated by healthy Chinese women. The pharmacokinetic profile of DNG was similar to that observed previously in healthy women of Caucasian and Korean origin. The favourable PK and safety results facilitate the use of Visanne™ in Chinese patients with endometriosis.

Keywords : Dienogest, single dose, multiple doses, endometriosis, pharmacokinetics, Chinese women

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