

## A comparative bioavailability study of two ibuprofen formulations after single-dose administration in healthy volunteers

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### Abstrak

Penelitian ini dilakukan untuk mengetahui apakah bioavailabilitas formulasi ibuprofen suppositoria 125 mg yang diproduksi oleh PT Kalbe Farma, Tbk. (Ibukal®) bioekivalen dengan produk yang sama dari komparatornya (Proris®). Parameter farmakokinetik yang dinilai dalam studi ini ialah luas daerah di bawah kurva kadar - waktu selama 10 jam (AUC<sub>0-t</sub>), luas daerah di bawah kurva kadar - waktu sampai waktu tak terhingga (AUC<sub>0-inf</sub>), kadar puncak (C<sub>max</sub>), dan waktu untuk mencapai kadar puncak (t<sub>max</sub>). Penelitian ini menggunakan rancangan menyilang acak, tersamar tunggal yang mengikutsertakan 12 sukarelawan dewasa sehat. Sukarelawan dipuasakan semalam dan keesokan harinya diberi 1 suppositoria obat uji (produk PT. Kalbe-Farma) atau 1 suppositoria obat pembanding (produk komparatornya). Contoh darah diambil pada jam ke 0 (kontrol), 20 min; 40 min; 1; 1,5; 2; 2,5; 3; 4; 6; 8; dan 10 jam setelah pemberian obat. Setelah 1 minggu periode washout, prosedur ini diulang dengan memberikan obat pembandingnya. Kadar obat ditentukan dengan kromatografi cair kinerja tinggi dengan detektor ultraviolet. Pada penelitian bioavailabilitas ini, rerata (SD) AUC<sub>0-t</sub>, AUC<sub>0-inf</sub>, C<sub>max</sub> dan t<sub>max</sub> dari obat uji masing-masing adalah 28,59(3,37) µg.jam.mL<sup>-1</sup>, 30,47(3,56) µg.jam.mL<sup>-1</sup>, 8,24(1,44) µg/mL, dan 1,33(0,44) jam. Rerata (SD) AUC<sub>0-t</sub>, AUC<sub>0-inf</sub>, C<sub>max</sub> dan t<sub>max</sub> dari obat pembanding masing-masing adalah 28,13(8,14) µg.jam.mL<sup>-1</sup>, 30,56(8,05) µg.jam.mL<sup>-1</sup>, 8,27(2,88) µg/mL, dan 1,79(0,33) jam. Rasio rerata geometrik obat uji terhadap obat pembandingnya ialah 104,38% untuk AUC<sub>0-t</sub>, 101,97% untuk AUC<sub>0-inf</sub>, dan 104,02% untuk C<sub>max</sub>, Nilai 90% confidence intervals(CI) nya ialah 90,38-120,54% untuk AUC<sub>0-t</sub>, 89,51-116,16% untuk AUC<sub>0-inf</sub>, dan 85,73-126,16% untuk C<sub>max</sub>. Tidak ada efek samping yang dijumpai dalam penelitian ini. Dari hasil penelitian ini disimpulkan bahwa Ibuprofen suppositoria 125 mg produksi PT. Kalbe Farma, Tbk. (Ibukal®) bioekuivalen dengan produk yang sama dari komparatornya (Proris®). (Med J Indones 2007; 16:181-6).

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This study was aimed to investigate the bioequivalence of ibuprofen 125 mg suppository formulation (Ibukal®, test formulation from PT. Kalbe Farma, Tbk., Jakarta) and the ibuprofen suppository comparative formulation (Proris®, from PT. Pharos Indonesia, Jakarta) in 12 healthy volunteers. The pharmacokinetic parameters used in this study were the area under the concentration-time curve from time zero to hour 10 (AUC<sub>0-t</sub>), the area under the concentration-time curve from time zero to infinite (AUC<sub>0-inf</sub>), the maximum concentration (C<sub>max</sub>), and the time needed to reach the maximum concentration (t<sub>max</sub>). The study was designed as a random cross-over fashion, single-blinded which included 12 healthy adult volunteers. The volunteers were fasted overnight and in the morning they received a suppository of the test drug (Ibukal®) or a suppository of the comparative drug (Proris®). Blood samples were withdrawn on hour 0 (control), 20 min; 40 min; 1; 1,5; 2; 2,5; 3; 4; 6; 8; and 10 time points after the administration of the drug. Following a wash-out period of 1 week, this procedure was repeated using the other drug. The serum concentration of the drug was determined by means of high-performance liquid chromatography with ultraviolet detection. The results of the study showed that, the mean (SD) of AUC<sub>0-t</sub>, AUC<sub>0-inf</sub>, C<sub>max</sub> and t<sub>max</sub> of the test drug

were, respectively, 28.59(3.37)  $\mu\text{g}\cdot\text{h}\cdot\text{mL}^{-1}$ , 30.47(3.56)  $\mu\text{g}\cdot\text{h}\cdot\text{mL}^{-1}$ , 8.24(1.44)  $\mu\text{g}/\text{mL}$ , and 1.33(0.44) h. The mean (SD) of AUC<sub>0-t</sub>, AUC<sub>0-inf</sub>, C<sub>max</sub> and t<sub>max</sub> of the comparative drug were, respectively, 28.13(8.14)  $\mu\text{g}\cdot\text{h}\cdot\text{mL}^{-1}$ , 30.56(8.05)  $\mu\text{g}\cdot\text{h}\cdot\text{mL}^{-1}$ , 8.27(2.88)  $\mu\text{g}/\text{mL}$ , and 1.79(0.33) h. The geometric means ratio of the test to the comparative drug were 104.38% (CI 90%: 90.38-120.54%) for AUC<sub>0-t</sub>, 101.97% (CI 90%: 89.51-116.16%) for AUC<sub>0-inf</sub>, and 104.02% (CI 90%: 85.73-126.16%) for C<sub>max</sub>. There was no side effect of the drug detected in this study. From the results we can conclude that the 125 mg of ibuprofen suppository of PT Kalbe Farma, Tbk. (Ibukal®) is bioequivalent to that of the comparative drug (Proris®). (Med J Indones 2007; 16:181-6)