Doribax®

Active ingredient: Doripenem
Marketing authorisation holder: Janssen-Cilag International NV
Availability: Private Sector

Variations: The pharmacokinetic section of the SmPC was updated with data for adult patients with cystic fibrosis about the pharmacokinetics of doripenem and its microbiologically inactive ring-opened metabolite (doripenem-M-1) after a single dose 1g or 2g 4-hour intravenous infusion. These patients were in stable condition and did not necessitate hospitalisation.

The information in the SmPC on the effect of gender on the pharmacokinetics of doripenem was also altered. The study was carried out in healthy participants. Although the AUC of doripenem was 13% higher in the female gender, no dosage adjustments are suggested.