

“No new safety concerns were identified for ceftaroline fosamil 600 mg 50 mL compared with 250 mL. These findings suggest infusion volumes down to 50 mL may be used in patients with fluid intake restrictions.” Edeki et al (2014).

Reference:

Edeki, T., Kujacic, M., Broadhurst, H., Li, J. and Sunzel, M. (2014) Safety, local tolerability and pharmacokinetics of ceftaroline fosamil administered in a reduced infusion volume. British Journal of Clinical Pharmacology. July 10th. .

Safety, local tolerability and pharmacokinetics of reduced volume ceftaroline
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Abstract:

AIMS: The standard dose of ceftaroline fosamil for patients with normal renal function is 600 mg diluted in 250 mL by 60 min intravenous infusion every 12 h (q12h). This 2-part Phase I trial (NCT01577589) assessed safety and local tolerability of multiple ceftaroline fosamil 50 mL and 250 mL infusions, and pharmacokinetics following single administrations of each infusion volume.

METHODS: Part A was a placebo-controlled, double-blind, multiple-dose crossover: 24 healthy subjects were randomized to simultaneous, bilateral ceftaroline fosamil 600 mg and placebo infusions in each arm (50 mL then 250 mL or vice versa) q12h for 72 h, with a ≥ 4.5 day washout. Local tolerability was evaluated by Visual Infusion Phlebitis scale, with scores ≥ 2 considered infusion site reactions (ISRs). Part B was an open-label crossover: 10 subjects were randomized to single 50 mL and 250 mL ceftaroline fosamil 600 mg infusions on Days 1 and 3 (washout on Day 2). Blood samples for pharmacokinetic analysis were taken over 24 h.

RESULTS: In part A, 4 subjects (16.7%) experienced ISRs, all of which were associated with placebo infusions; no ISRs were reported for either ceftaroline fosamil 50 mL or 250 mL. Plasma pharmacokinetics (ceftaroline fosamil, active ceftaroline and an inactive metabolite) were similar following single 50 mL and 250 mL infusions in Part B.

CONCLUSIONS: No new safety concerns were identified for ceftaroline fosamil 600 mg 50 mL compared with 250 mL. These findings suggest infusion volumes down to 50 mL may be

used in patients with fluid intake restrictions.

Other intravenous and vascular access resources that may be of interest (External links - IVTEAM has no responsibility for content).

- [Guide for intravenous chemotherapy and associated vascular access devices from Macmillan.](#)
- [CancerUK IV chemotherapy information.](#)

