Safety assessment of coenzyme Q10 (Kaneka Q10) in healthy subjects: a double-blind, randomized, placebo-controlled trial.

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Abstract

The safety profile of Coenzyme Q10 (Kaneka Q10) at high doses for healthy subjects was assessed in a double-blind, randomized, placebo-controlled study. Kaneka Q10 in capsule form was taken for 4 weeks at doses of 300, 600, and 900 mg/day by a total of eighty-eight adult volunteers. No serious adverse events were observed in any group. Adverse events were reported in 16 volunteers with placebo, in 12 volunteers with the 300 mg dose, in 20 volunteers with the 600 mg dose and in 16 volunteers with the 900 mg dose. The most commonly reported events included common cold symptoms and gastrointestinal effects such as abdominal pain and soft feces. These events exhibited no dose-dependency and were judged to have no relationship to Kaneka Q10. Changes observed in hematology, blood biochemistry, and urinalysis were not dose-related and were judged not to be clinically significant. The plasma CoQ10 concentration after 8-month withdrawal was almost the same as that before administration. These findings showed that Kaneka Q10 was well-tolerated and safe for healthy adults at intake of up to 900 mg/day.

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