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Study on safety and bioavailability of ubiquinol (Kaneka QH) after single and 4-week multiple oral administration to healthy volunteers.

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Abstract

The safety and bioavailability of ubiquinol (the reduced form of coenzyme Q(10)), a naturally occurring lipid-soluble nutrient, were evaluated for the first time in single-blind, placebo-controlled studies with healthy subjects after administration of a single oral dose of 150 or 300 mg and after oral administration of 90, 150, or 300 mg for 4 weeks. No clinically relevant changes in results of standard laboratory tests, physical examination, vital signs, or ECG induced by ubiquinol were observed in any dosage groups. The C(max) and AUC(0-48 h) derived from the mean plasma ubiquinol concentration-time curves increased non-linearly with dose from 1.88 to 3.19 micro g/ml and from 74.61 to 91.76 micro g h/ml, respectively, after single administration. Trough concentrations had nearly plateaued at levels of 2.61 micro g/ml for 90 mg, 3.66 micro g/ml for 150 mg, and 6.53 micro g/ml for 300 mg at day 14, and increased non-linearly with dose in the 4-week study. In conclusion, following single or multiple-doses of ubiquinol in healthy volunteers, significant absorption of ubiquinol from the gastrointestinal tract was observed, and no safety concerns were noted on standard laboratory tests for safety or on assessment of adverse events for doses of up to 300 mg for up to 2 weeks after treatment completion.

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