Risk assessment for coenzyme Q10 (Ubiquinone).
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Abstract
Coenzyme Q10 (CoQ10) widely occurs in organisms and tissues, and is produced and used as both a drug and dietary supplement. Increasing evidence of health benefits of orally administered CoQ10 are leading to daily consumption in larger amounts, and this increase justifies research and risk assessment to evaluate the safety. A large number of clinical trials have been conducted using a range of CoQ10 doses. Reports of nausea and other adverse gastrointestinal effects of CoQ10 cannot be causally related to the active ingredient because there is no dose-response relationship: the adverse effects are no more common at daily intakes of 1200 mg than at a 60 mg. Systematic evaluation of the research designs and data do not provide a basis for risk assessment and the usual safe upper level of intake (UL) derived from it unless the newer methods described as the observed safe level (OSL) or highest observed intake (HOI) are utilized. The OSL risk assessment method indicates that the evidence of safety is strong at intakes up to 1200 mg/day, and this level is identified as the OSL. Much higher levels have been tested without adverse effects and may be safe, but the data for intakes above 1200 mg/day are not sufficient for a confident conclusion of safety.

PMID: 16814438 [PubMed - indexed for MEDLINE]