

# Does methylphenidate cause liver damage? An analysis of ad hoc reports to the "Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)"

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## Abstract

Does methylphenidate cause liver damage? An analysis of ad hoc reports to the "Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)" Abstract. Ad hoc reports to the "Bundesinstitut für Arzneimittel und Medizinprodukte" (BfArM, the German Federal Institute for Drugs and Medical Devices) were analyzed concerning liver injuring stemming from therapy with methylphenidate (MPH). Clinical criteria were used to assess suspected cases of causal association. The BfArM database on adverse drug reactions (ADRs) recorded suspected cases from Germany over the period from 1 January 2006 to 23 May 2016. Using the Standardized MedDRA Queries (SMQ) search strategy, we searched the database for "MPH" and its potential ADRs "Hepatic Disorder." The ad hoc reports were checked for completeness and assessed clinically according to the Uppsala Monitoring Centre criteria. 60 suspected cases of liver damages by MPH were recorded in the database. In 15 thereof, an assessment was not possible because of insufficient documentation; in 25 cases, a link between the intake of MPH and the occurrence of liver injury was considered "unlikely." A "possible" causality was assessed in 11 cases, a "probable/likely" causality in 9 cases: 1 patient with fulminant hepatitis, 1 with increased size of benign liver tumor, and 18 cases of (reversible) hepatic enzyme elevation. According to our evaluation, MPH is well-tolerated with regard to liver and gall bladder diseases. For patients with hepatic impairment or other risk factors, regular monitoring of liver values is recommended.