

Safety Reports

Acetaminophen (APAP)

Introductory Statement

The source of these reports are primarily from the FDA's Adverse Event Reporting System (AERS) and/or the published medical literature. AERS is a spontaneous, voluntary surveillance system. Reports are voluntarily reported by health care professionals and consumers to either the FDA directly or to the manufacturer. The manufacturer is required to submit these reports to the Agency for products with an NDA.

Liver Injury related to Acetaminophen (APAP)

307 US cases of liver injury reported in association with one or more acetaminophen-containing drug products received by the Agency from Jan 1998 to July 2001. These include cases of unintentional overdose, accidental overdose, therapeutic error, abuse and misuse, or those where intention was unknown. Cases with obvious evidence of suicidal intention were excluded.

(Click on the ISR number in the Acetaminophen Safety Reports Index for the complete Safety Report)