

June 17, 2015 - 08.48

/\*\* You can annotate your report here... \*\*/

Type of liver injury	: Cholestatic/mixed
Time of onset of the event	: First exposure
Time from drug intake until reaction onset	: 5 to 90 days [+2]
Time from drug withdrawal until reaction onset	: >30 days [0]
Alcohol or pregnancy risk factor	: Present [+1]
Age risk factor	: ≥55 years [+1]
Course of the reaction	: ≥50% improvement 180 days [+2]
Concomitant therapy	: Time to onset compatible but with unknown reaction [-1]
Exclusion of non drug-related causes	: Rule out [+2]
Previous information on hepatotoxicity	: Reaction published but unlabeled [+1]
Response to re-administration	: Compatible [+1]

Score: 9

Highly probable ADR

REFERENCES: Danan G, Benichou C. Causality assessment of adverse reactions to drugs--I. A novel method based on the conclusions of international consensus meetings: application to drug-induced liver injuries. J Clin Epidemiol. 1993;46(11):1323-30. Pubmed PMID: 8229110 (<http://www.ncbi.nlm.nih.gov/pubmed/8229110>)