

Table. Reported Hepatotoxicity in Head-to-Head Trials Involving Telithromycin*

Study, Year (Reference)	Comparator	Indication	Patients, <i>n</i>	Total Rate of Adverse Events in the Telithromycin Group versus the Comparator Group, %/%	Hepatic Adverse Events with Telithromycin versus the Comparator	
					Events, <i>n/n</i>	Description
Hagberg et al., 2002 (2)	High-dose amoxicillin	CAP	404	55.3/45.9	17/14	Abnormal results on liver function tests; ALT level increased to 3 × ULN
Norrby et al., 2001(12)	Penicillin V	Tonsillitis or pharyngitis	395	35.4/35.2	0/1	ALT level increased to 3 × ULN
Luterman et al., 2003(10)	Amoxicillin-- clavulanate	Sinusitis	754	42.2/46.9/ 42.9†	NA	No hepatic differences between groups
Quinn et al., 2003(14)	Clarithromycin	Tonsillitis or pharyngitis	463	67.2/57.5 (<i>P</i> < 0.05)	1/0	ALT, AST, and LDH levels increased 2.9, 7.6, and 2.5 × ULN, respectively
Buchanan et al., 2003(9)	Cefuroxime	Sinusitis	593	36.1/31.4	NA	No hepatic differences between groups
Pullman et al., 2003(13)	Trovafloxacin	CAP	223	47.2/33.0 (<i>P</i> = 0.038)	5/0	Abnormal results on liver function tests; AST level increased to 3 × ULN
Zervos et al., 2003 (15)	Cefuroxime	Acute exacerbation of chronic bronchitis	373	30/32.3	1/0	ALT level increased to 3 × ULN
Mathers Dunbar et al., 2004 (11)	Clarithromycin	CAP	416	57/49	1/0	ALT level, 418 U/L; AST level, 295 U/L
Aubier et al., 2002 (16)	Amoxicillin-- clavulanate	Acute exacerbation of chronic bronchitis	325	23.8/36.9 (<i>P</i> = 0.015)	NA	No laboratory safety differences between groups
Ferguson et al., 2004(17)	Moxifloxacin	Sinusitis	349	34.7/27.8	NA	No hepatic differences between groups
Tellier et al., 2004 (18)	Clarithromycin	CAP	575	44.6/44.9	10/7	Elevated levels of ALT and AST

*ALT= alanine aminotransferase; AST= aspartate aminotransferase; CAP = community-acquired pneumonia; LDH= lactate dehydrogenase; NA = not available; ULN = upper limit of normal.

† This study involved 2 telithromycin groups, one that received the drug for 5 days and another that received the drug for 10 days. The first 2 values given are for these 2 groups, respectively.