1: Birth Defects Res A Clin Mol Teratol. 2005 Nov;73(11):888-96. Related Articles, Links

Pregnancy outcomes after maternal exposure to simvastatin and lovastatin.

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BACKGROUND: Our objective was to determine the frequency of adverse outcomes after maternal exposure to simvastatin and/or lovastatin during pregnancy in postmarketing experience. METHODS: We reviewed the Merck & Co., Inc. (West Point, PA) pharmacovigilance database for reports of exposure to simvastatin or lovastatin during pregnancy. The reports were classified as prospective (reported prior to pregnancy outcome) or retrospective (reported after pregnancy outcome) and

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were evaluated for timing of exposure, outcome, congenital anomalies, and other events. Outcome rates were calculated for prospective pregnancies. RESULTS: We identified 477 reports (386 prospective and 91 retrospective) with 225 prospective outcomes reported: 154 live born infants, 49 elective abortions, 18 spontaneous abortions, and 4 fetal deaths. Six congenital anomalies were reported: chromosomal translocation, trisomy 18, hypospadias, duodenal atresia, cleft lip, and skin tag. The rate of congenital anomalies (congenital anomalies/live births plus fetal deaths) was 3.8%, which is similar to the background population rate (3.2%; relative ratio, 1.21; 95% 1-sided upper confidence interval [CI], 2.02). There were 13 retrospective reports describing a range of congenital anomalies. No specific pattern of anomalies was identified in either the prospective or retrospective reports. Rates for other outcomes were similar to background rates. CONCLUSIONS: Although the number of reports was relatively small, there was no evidence of a notable increase in congenital anomalies in women exposed to simvastatin or lovastatin versus the general population. Greater reporting of congenital abnormalities in the retrospective cohort is not unexpected and may reflect a reporting bias. Drugs should be used during pregnancy only if the benefits outweigh the risks. Simvastatin and lovastatin remain contraindicated during pregnancy.

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