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two decades but the overall total prevalence of major malformations has been unchanged.8-10 Other studies have reported a gradual decline in the total prevalence of nonchromosomal and an increase in chromosomal anomalies.11,12 No consistent evidence of seasonality has been reported for common birth defect groups.13 A higher overall rate of birth defects is reported in males and black infants.14,15 Another study from the UK reported a higher risk of congenital anomalies of nonchromosomal ...

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European Medicines Agency: Pharmacovigilance Risk Assessment Committee. New product information wording—extracts from PRAC recommendations on signals: 2. modafinil—evaluation of data on foetal outcomes including congenital anomalies from a single observational study in the US (EPITT No. 19367). Accessed February 26, 2020.

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