HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Methylphenidate-containing medicines: Small increased risk of cardiac malformations in infants exposed during the first trimester of pregnancy

The HPRA would like to highlight a recommendation made by the European Medicines Agency's (EMA's) Pharmacovigilance Risk Assessment Committee, to update product information* for methylphenidate-containing medicines.

Methylphenidate is a centrally acting sympathomimetic which is indicated in the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children between 6 and 18 years and also adults. Data from a large cohort study[1] of approximately 3,400 pregnancies has shown a small increased occurrence of cardiac malformations (pooled adjusted relative risk, 1.3; 95% CI, 1.0-1.6) in infants exposed to methylphenidate during the first trimester of pregnancy compared with non-exposed pregnancies. However, the study did not show an increased risk of overall birth defects. The product information* has been updated to reflect the data.

Healthcare professionals (HCPs) are reminded that methylphenidate-containing medicines are not recommended for use during pregnancy unless there is a clinical decision that postponing treatment may pose a greater risk to the pregnancy.

HCPs are reminded to regularly check the HPRA or EMA websites for current product information concerning medicines they prescribe or dispense.

Reference:

1. Huybrechts K, Broms G, Christensen L, et al. Association between methylphenidate and amphtetamine use in pregnancy and risk of congenital malformations. JAMA Psychiatry December 2017.

**The approved product information is made up of the Summary of Product Characteristics (SmPC) and Package Leaflet (PL) and is available at www.hpra.ie and www.ema.europa.eu.*

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