

Lyrice Use During Pregnancy Increases The Risk Of Major Birth Defects

(Posted by Tom Lamb at www.DrugInjuryWatch.com on May 23, 2016)

Women who took Lyrice (pregabalin) while pregnant were about three times more likely to have babies with major birth defects compared with women who did not take Lyrice, according to study done by a team of medical researchers in Europe that was recently reported in the journal *Neurology*.

From the Abstract for this report, "Pregnancy outcome following maternal exposure to pregabalin may call for concern", from the Neurology.org website ("Published online before print May 18, 2016") we get an overview of the new Lyrice research:

Objective: To investigate pregnancy outcomes following maternal use of [Lyrice (pregabalin)].

Methods: This multicenter, observational prospective cohort study compared pregnancy outcomes in women exposed to [Lyrice (pregabalin)] with those of matched controls (not exposed to any medications known to be teratogenic or to any antiepileptic drugs)...

Conclusions: This study demonstrated a signal for increased risk of major birth defects after first trimester exposure to [Lyrice (pregabalin)]. However, several limitations such as the small sample size, differences across groups in maternal conditions, and concomitant medication exposure exclude definitive conclusions, so these results call for confirmation through independent studies.

From a May 19, 2016 *Medpage Today* article, "Human Birth Defects Seen With Pregabalin -- Time for a pregnancy category change?", we get this contextual information and commentary about this recent Lyrice - birth defects medical study:

The FDA currently classifies [Lyrice (pregabalin)] as pregnancy category C, indicating that teratogenic effects have been seen in animal studies but there are "no adequate and well controlled studies in pregnant women." Whether the agency will revise [Lyrice (pregabalin)]'s label on the basis of the new study remains to be seen.

Max Wiznitzer, MD, of UH Rainbow Babies and Children's Hospital in Cleveland, who was not involved in the study, said it raises important questions, but is "not definitive proof" that [Lyrice (pregabalin)] causes these birth defects because the study was small,

doesn't hone in on a single defect or syndrome and included many mothers-to-be who were also taking other medications. He said it warranted further research.

We will continue to monitor the medical literature for any more research done on this drug safety issue of pregnant women using Lyrica having an increased risk of having children with birth defects. We will also watch to see whether the FDA decides there should be any Lyrica label change, such as changing the pregnancy category for Lyrica.

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Attorney [Tom Lamb](#) represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
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