



## A study questions the safety of pregabalin during pregnancy

**Treatment with pregabalin (Lyrica® or generica) in pregnant women could put the fetus at serious risk. A study led by the STIS and published in *Neurology* found an increased frequency of major malformations following exposure to pregabalin during the first trimester of pregnancy.**

The STIS coordinated a multicenter study involving eight member centers of the European Network for Teratovigilance Information Services (ENTIS), which aimed at recording the incidence of malformations after pregabalin use during the first trimester of pregnancy [1]. Pregabalin, an anti-seizure drug, is most frequently used to treat chronic pain and anxiety disorders. This study is now published in *Neurology*, the official journal of the American Academy of Neurology.

The study compared the outcome of pregnancy in 164 patients exposed to pregabalin and in a control group of 656 women not exposed to problematic drugs during pregnancy. A higher rate of major malformations was observed in the fetuses exposed to pregabalin during the first trimester compared to the control group (6% versus 2.1%). Since this is the first warning questioning the reproductive safety of this medication and because of the limitations of the study (sample size, between-group differences in coexisting diseases and drug treatments), the authors stress that this finding still needs to be confirmed by other independent studies.

However, the significant increase in the rate of malformations observed in this study presently implies that pregabalin prescription be avoided whenever possible during pregnancy. In patients of childbearing age, effective contraception should be advised when prescribing pregabalin, and its indication must be carefully re-examined in cases of desired or established unexpected pregnancy. A detailed morphological ultrasound examination is recommended following exposure to pregabalin during the first trimester of pregnancy.

### Reference :

Winterfeld U, Merlob P, Baud D, Rousson V, Panchaud A, Rothuizen LE, Bernard N, Vial T, Yates LM, Pistelli A, Ellfolk M, Eleftheriou G, de Vries LC, Jonville-Bera A-P, Kadioglu M, Biollaz J, Buclin T. Pregnancy outcome following maternal exposure to pregabalin may call for concern. Published online before print May 18, 2016, doi: <http://dx.doi.org/10.1212/WNL.0000000000002767> *Neurology* 10.1212/WNL.0000000000002767

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