



## **Dolutegravir and risk of neural tube defects.**

WHO, the European Medicines Agency, the US Food and Drug Administration, and Swissmedic issue a warning about the possible risk of neural tube defects after exposure to dolutegravir (Tivicay<sup>®</sup>, Triumeq<sup>®</sup>) during early pregnancy.

Preliminary results from an ongoing observational surveillance study of birth outcomes among pregnant women on antiretroviral therapy in Botswana, showed that 0.9% (4/426) newborns whose mothers were taking dolutegravir at the time of conception had a neural tube defect compared with 0.1% (14/11'173) newborns of mothers who took other HIV treatments [1]. An analysis from the same study found no significant differences between dolutegravir (280) and efavirenz-based (395) treatment regimens on any adverse birth outcomes in women who started treatment during pregnancy, and no neural tube defects were identified [2]. In the upcoming months, further data from this study will provide more information.

Limited previously published data did not indicate any clear safety signals for pregnant women treated with dolutegravir in terms of congenital anomalies and other birth outcomes [3]. However, there is only limited safety data available to support the use of dolutegravir during pregnancy. Further studies on dolutegravir during pregnancy are necessary.

### References:

1. World Health Organization. Potential safety issue affecting women living with HIV using dolutegravir at the time of conception. Geneva, Switzerland. May 18, 2018.
2. Zash R, Jacobson DL, Diseko M, Mayondi G, Mmalane M, Essex M, Gaolethe T, Petlo C, Lockman S, Holmes LB, Makhema J, Shapiro RL. Comparative safety of dolutegravir-based or efavirenz-based antiretroviral treatment started during pregnancy in Botswana: an observational study. *Lancet Glob Health*. 2018 Jul;6(7):e804-e810.
3. Hill A, Clayden P, Thorne C, Christie R, Zash R. Safety and pharmacokinetics of dolutegravir in HIV-positive pregnant women: a systematic review. *J Virus Erad*. 2018 Apr 1;4(2):66-71.

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