



Tivicay May Cause Birth Defects if Taken During First Trimester

The integrase inhibitor is included in the single-tablet HIV regimens Triumeq and Juluca.

May 22, 2018 By [Benjamin Ryan](#)

The Food and Drug Administration (FDA) has issued a warning to women living with HIV that the antiretroviral Tivicay (dolutegravir) may cause birth defects if taken during conception or the first trimester of pregnancy, Medscape reports.

Tivicay is an integrase inhibitor that is included in the single-tablet regimens Triumeq (dolutegravir/abacavir/lamivudine) and Juluca (dolutegravir/rilpivirine).

The FDA advises women of childbearing age to undergo a pregnancy test before beginning an HIV regimen including Tivicay and to consistently use contraception if they are taking the drug.

Women who are currently taking Tivicay should not stop the drug without the guidance of their health care provider.

This warning is based on preliminary findings of a study conducted in Botswana that included 11,558 HIV-positive women. A total of 426 women became pregnant while taking Tivicay, resulting in four infants (0.9 percent) who were born with neural tube defects such as spina bifida. By comparison, 14 infants (0.1 percent) were born to 11,173 mothers taking HIV regimens that did not include Tivicay. The final results from this study are expected in about a year.

Women who took Tivicay at conception or during their first trimester appeared to be at higher risk for such birth defects in their newborns. No women who took the drug only past the first trimester gave birth to infants with these defects.

To read the Medscape article, [click here](#) (free registration with the site is required).

To read the FDA breakdown of the warning, [click here](#).
