

Dolutegravir-containing products – Safety communication

- On May 18, 2018, the [FDA announced](#) that serious cases of neural tube birth defects have been reported in babies born to women treated with dolutegravir.
 - Neural tube defects are birth defects that can occur early in pregnancy, when the spinal cord, brain and related structures do not form properly.
 - Preliminary results from an ongoing observational study in Botswana found that women who received dolutegravir at the time of becoming pregnant or early in the first trimester appear to be at higher risk for these defects.
- Medications that contain dolutegravir include [Juluca[®] \(dolutegravir/rilpivirine\)](#), [Tivicay[®] \(dolutegravir\)](#), and [Triumeq[®] \(abacavir/dolutegravir/lamivudine\)](#). These drugs are used in combination with other antiretroviral medicines to treat human immunodeficiency virus (HIV) infection. Refer to the drug labels for further indication information.
- Patients should not stop taking dolutegravir without first talking to their healthcare provider as this can cause the HIV infection to worsen.
- If a patient is already pregnant, stopping dolutegravir-containing therapy without switching to an alternative HIV medicine could cause the amount of virus to increase and spread HIV to the baby.
- If a patient is taking a dolutegravir-containing regimen at the time of becoming pregnant and during the first trimester, there is a risk that the baby may develop neural tube defects.
 - Neural tube defects occur early in pregnancy, before many women even know they are pregnant. Women of childbearing age should talk to their healthcare provider about other non-dolutegravir-containing antiretroviral medicines.
 - Patients should notify their healthcare provider if they are pregnant or planning to become pregnant before starting a dolutegravir-containing regimen.
 - Women of childbearing age who decide to take a dolutegravir-containing regimen should consistently use effective contraception while on HIV treatment. Women should talk to their healthcare provider about effective contraception options.
 - A pregnancy test is needed prior to starting a dolutegravir-containing regimen.
- Healthcare providers should inform women of childbearing age about the potential risk of neural tube defects when a dolutegravir-containing regimen is used at the time of conception and early in pregnancy.
 - Healthcare providers should perform a pregnancy test prior to initiating a dolutegravir regimen and reinforce the consistent use of effective birth control in women of child-bearing age if the dolutegravir therapy is prescribed.
 - The benefits and risks of dolutegravir and alternative therapies should be considered when prescribing antiretroviral medicines to women of childbearing age.