



FDA Drug Safety Communication

FDA to evaluate potential risk of neural tube birth defects with HIV medicine dolutegravir (Juluca, Tivicay, Triumeq)

Safety Announcement

[05-18-2018] The U.S. Food and Drug Administration (FDA) is alerting the public that serious cases of neural tube birth defects involving the brain, spine, and spinal cord have been reported in babies born to women treated with dolutegravir used to treat human immunodeficiency virus (HIV). 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.

Neural tube defects are birth defects that can occur early in pregnancy when the spinal cord, brain, and related structures do not form properly. To date, in this observational study there are no reported cases of babies born with neural tube defects to women starting dolutegravir later in pregnancy. We are investigating this new safety issue and will update the public when we have more information.

Dolutegravir is an FDA-approved antiretroviral medicine used in combination with other antiretroviral medicines to treat HIV, the virus that can cause acquired immunodeficiency syndrome (AIDS). Dolutegravir works by blocking integrase, an HIV enzyme, to prevent the virus from multiplying and can reduce the amount of HIV in the body. Stopping dolutegravir without first talking to a prescriber can cause the HIV infection to become worse. Approved in 2013, dolutegravir has been on the market for 5 years, and is available as a single ingredient product under the brand name Tivicay and as a fixed dose combination tablet with other HIV medicines under the brand names Juluca and Triumeq.

Patients should not stop taking dolutegravir without first talking to your health care professional because stopping your medicine can cause the HIV infection to worsen. In addition:

- If you are already pregnant, stopping your dolutegravir-containing regimen without switching to alternative HIV medicines could cause the amount of virus to increase and spread HIV to your baby.
- If you take a dolutegravir-containing regimen at the time of becoming pregnant and during the first trimester of pregnancy, there is a risk that your baby may develop neural tube defects. Neural tube defects happen early in pregnancy, before many women even know they are pregnant. For this reason, women of childbearing age should talk to their health care professional about other non-dolutegravir-containing antiretroviral medicines.

- You should tell your health care professional if you are pregnant or are planning to become pregnant before you start a dolutegravir-containing regimen. Your health care professional may discuss other treatment options with you.
- Women of childbearing age who decide to take a dolutegravir-containing regimen should consistently use effective birth control (contraception) while on HIV treatment. Women should talk to their health care professionals about an effective birth control method to use while taking a dolutegravir-containing regimen.
- Before you start a dolutegravir-containing regimen you will need a pregnancy test to determine if you are already pregnant.

Health care professionals 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. In addition:

- Health care professionals should weigh the benefits and the risks of dolutegravir when prescribing antiretroviral medicines to women of childbearing age. Alternative antiretroviral medicines should be considered. Discuss the relative risks and benefits of appropriate alternative antiretroviral therapies.
- If the decision is made to use dolutegravir in women of childbearing age, health care professionals should reinforce the consistent use of effective birth control.
- Perform pregnancy testing before initiating a dolutegravir-containing regimen in women of childbearing age to exclude pregnancy.

Ongoing monitoring will continue as part of the observational study in Botswana. Additional birth outcomes are projected from pregnant women who were exposed to dolutegravir at the time of becoming pregnant. We will conduct a comprehensive review of the results and any other data that becomes available. We will update the public with any new information. To monitor birth outcomes of pregnant women, report pregnancy exposures to the Antiretroviral Pregnancy Registry at 1-800-258-4263.

We urge health care professionals and patients to report side effects involving dolutegravir or other medicines to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of the page.

Related Information

- [Neural Tube Defects](#)
- [Anencephaly](#)
- [Spina Bifida](#)
- [The FDA’s Drug Review Process: Ensuring Drugs Are Safe and Effective](#)
- [Think It Through: Managing the Benefits and Risks of Medicines](#)