Generic Name:
Dolutegravir-containing medications
Trade Name:
Tivicay, Juluca, Triumeq
Company:
ViiV Healthcare
Notes:

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, an antiretroviral medication used to treat HIV. 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 medications under the brand names Juluca and Triumeq.

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 appeared to be at higher risk for these defects.

Health 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.

Patients should not stop taking dolutegravir without first talking to their health professional because stopping the medicine can cause the HIV infection to worsen. Stopping dolutegravir without first talking to a prescriber can cause the HIV infection to become worse.

More information is available on FDA's website.

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. FDA said it is investigating this new safety issue and will update the public when it has more information. Ongoing monitoring will continue as part of the observational study in Botswana.

Medication Monitor Categories:
Alerts and Recalls