

BIKTARVY: recent changes to labeling

HIV Email Updates



August 6, 2019

FDA recently approved changes to the BIKTARVY (bictegravir) product labeling. Section 8.1 Pregnancy was updated to include the following text under Risk Summary and Human Data.

Risk Summary

Dolutegravir, another integrase inhibitor, has been associated with neural tube defects (NTDs) (see Data). Discuss the benefit-risk of using BIKTARVY with individuals of childbearing potential, particularly if pregnancy is being planned.

Data

Human Data

Bictegravir: Data from an observational study in Botswana showed that dolutegravir, another integrase inhibitor, was associated with increased risk of neural tube defects when administered at the time of conception and in early pregnancy. Data available to date from other sources including the APR, clinical trials, and postmarketing data are insufficient to address this risk with BIC.

The updated label will soon be available at Drugs@FDA or [DailyMed](#)

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