RXADVANCE
2 Park Central Drive
Southborough, MA 01772

CLINICAL UPDATE

Brand Name	TIVICAY PD
Generic Name	dolutegravir
Drug Manufacturer	ViiV Healthcare

Indications for Use

TIVICAY and TIVICAY PD are a human immunodeficiency virus type 1 (HIV-1) integrase strand transfer inhibitor (INSTI) indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults (treatment-naïve or -experienced) and in pediatric patients (treatment-naïve or -experienced but INSTI- naïve) aged at least 4 weeks and weighing at least 3 kg.

TIVICAY is indicated in combination with rilpivirine as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure or known substitutions associated with resistance to either antiretroviral agent.

US Food & Drug Administration (FDA) Review Designation

Include FDA approval date, review designation, type of review, dispensing restrictions, etc.

Original FDA Approval Date: August 12, 2013 for TIVICAY

Updated FDA Approval Date: June 12, 2020 for TIVICAY PD

Safety

ADVERSE EVENTS

The most common adverse reactions of moderate to severe intensity and incidence at least 2% (in those receiving TIVICAY in any one adult trial) are insomnia, fatigue, and headache.

WARNINGS & PRECAUTIONS

- Hypersensitivity reactions characterized by rash, constitutional findings, and sometimes organ dysfunction, including liver injury, have been reported. Discontinue TIVICAY or TIVICAY PD and other suspect agents immediately if signs or symptoms of hypersensitivity reactions develop, as a delay in stopping treatment may result in a life-threatening reaction.
- Hepatotoxicity has been reported in patients receiving dolutegravir-containing regimens. Patients with underlying hepatitis B or C may be at increased risk for worsening or development of transaminase elevations. Monitoring for hepatotoxicity is recommended.
- Embryo-fetal toxicity may occur when used at the time of conception and in early pregnancy. An alternative treatment to dolutegravir should be considered at the time of conception through the first trimester of pregnancy due to the risk of neural tube defects. Counsel adolescents and adults of childbearing potential to use effective contraception.
- Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy.
- TIVICAY tablets and TIVICAY PD tablets for oral suspension are not interchangeable.

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Drug Interactions

- Drugs that are metabolic inducers may decrease the plasma concentrations of dolutegravir.
- TIVICAY or TIVICAY PD should be taken 2 hours before or 6 hours after taking cation-containing antacids or laxatives, sucralfate, oral supplements containing iron or calcium, or buffered medications. When taken with food, TIVICAY and supplements containing calcium or iron can be taken at the same time.

Special Population Considerations

PEDIATRICS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study(ies) requirement for ages 0 to less than 4 weeks of age because necessary studies are impossible or highly impracticable. This is because with improvement in perinatal transmission prevention strategies there are insufficient numbers of neonatal subjects to be enrolled. Further even when neonates are identified for enrollment, by the time enrollment is accomplished, dosing is initiated, and drug concentrations have reached steady state, the subjects are likely to be older than 4 weeks of age.

PREGNANCY

An alternative treatment to dolutegravir should be considered at the time of conception through the first trimester due to the risk of neural tube defects.

LACTATION

Breastfeeding is not recommended due to the potential for HIV-1 transmission.

FEMALES & MALES OF REPRODUCTIVE POTENTIAL

Pregnancy testing and contraception are recommended in adolescents and adults of childbearing potential.

Product Availability

DOSAGE FORM(S) & STRENGTH(S)

TIVICAY PD tablets for oral suspension: 5 mg