Dovato

dolutegravir 50 mg/
lamivudine 300 mg tablets

ViiV HEALTHCARE PRESENTS

An Educational Event in the DOVATO Speaker Series

Treating Virologically Suppressed Patients: Key Study Data

PRESENTED BY:

Caleb Youngblood, PA-C

Speaker compensated or employed by ViiV Healthcare

EVENT DATE:

Wednesday, September 18, 2024

6:00 PM - EST

EVENT LOCATION:

The Capital Grille

2800 West Big Beaver Rd.

Troy, Michigan 48084

Scan the QR code to register for this program.

Please RSVP by contacting your ViiV Representative

Deborah El-Amin

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Please RSVP by: **September 13, 2024**

INDICATION

DOVATO is indicated as a complete regimen to treat HIV-1 infection in adults with no antiretroviral (ARV) treatment history or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable ARV regimen with no history of treatment failure and no known resistance to any component of DOVATO.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: PATIENTS CO-INFECTED WITH HEPATITIS B VIRUS (HBV) AND HIV-1: EMERGENCE OF LAMIVUDINE-RESISTANT HBV AND EXACERBATIONS OF HBV

All patients with HIV-1 should be tested for the presence of HBV prior to or when initiating DOVATO. Emergence of lamivudine-resistant HBV variants associated with lamivudine-containing antiretroviral regimens has been reported. If DOVATO is used in patients co-infected with HIV-1 and HBV, additional treatment should be considered for appropriate treatment of chronic HBV; otherwise, consider an alternative regimen.

Severe acute exacerbations of HBV have been reported in patients who are co-infected with HIV-1 and HBV and have discontinued lamivudine, a component of DOVATO. Closely monitor hepatic function in these patients and, if appropriate, initiate anti-HBV treatment.

Please see additional Important Safety Information for DOVATO throughout.
Please see accompanying full Prescribing Information, including Boxed Warning, for DOVATO.

IMPORTANT SAFETY INFORMATION (cont'd)

Contraindications

- Do not use DOVATO in patients with previous hypersensitivity reaction to dolutegravir or lamivudine
- Do not use DOVATO in patients receiving dofetilide

Warnings and precautions

Hypersensitivity Reactions:

- Hypersensitivity reactions have been reported with dolutegravir and were characterized by rash, constitutional findings, and sometimes organ dysfunction, including liver injury
- Discontinue DOVATO immediately of signs or symptoms of severe skin or hypersensitivity reactions develop, as a delay in stopping treatment may result in a life-threatening reaction. Clinical status, including liver aminotransferases, should be monitored and appropriate therapy initiated

Hepatotoxicity:

- Hepatic adverse events have been reported, including cases of hepatic toxicity (elevated serum liver biochemistries, hepatitis, and acute liver failure), in patients receiving a dolutegravir-containing regimen without pre-existing hepatic disease or other identifiable risk factors
- Patients with underlying hepatitis B or C or marked elevations in transaminases prior to treatment may be at increased risk for worsening or development of transaminase elevations with use of DOVATO. In some cases, the elevations in transaminases were consistent with immune reconstitution syndrome or hepatitis B reactivation, particularly in the setting where anti-hepatitis therapy was withdrawn
- Monitoring for hepatotoxicity is recommended

Embryo Fetal Toxicity:

- Assess the risks and benefits of DOVATO and discuss with the patient to determine if an alternative treatment should be considered at the time of conception through the first trimester of pregnancy due to the risk of neural tube defects
- Pregnancy testing is recommended before initiation of DOVATO. Individuals of childbearing potential should be counseled on the consistent use of effective contraception

Lactic Acidosis and Severe Hepatomegaly With Steatosis: Fatal cases have been reported with the use of nucleoside analogs, including lamivudine. Discontinue DOVATO if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

Adverse Reactions or Loss of Virologic Response Due to Drug Interactions with concomitant use of DOVATO and other drugs may occur (see Contraindications and Drug interactions).

Immune Reconstitution Syndrome, including the occurrence of autoimmune disorders with variable time to onset, has been reported with the use of DOVATO.

Adverse reactions

The most common adverse reactions (incidence ≥2%, all grades) with DOVATO were headache (3%), nausea (2%), diarrhea (2%), insomnia (2%), fatigue (2%), and anxiety (2%).

Drug interactions

- Consult full Prescribing Information for DOVATO for more information on potentially significant drug interactions
- DOVATO is a complete regiment. Coadministration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended
- Drugs that induce or inhibit CYP3A or UGT1A1 may affect the plasma concentrations of dolutegravir
- Administer DOVATO 2 hours before or 6 hours after taking polyvalent cation-containing antacids or laxatives, sucralfate, oral supplements containing iron or calcium, or buffered medications. Alternatively, DOVATO and supplements containing calcium or iron can be taken with food

Use in specific populations

- **Pregnancy:** There are insufficient human data on the use of DOVATO during pregnancy to definitively assess a drug-associated risk for birth defects and miscarriage. An Antiretroviral Pregnancy Registry has been established. Advise individuals of childbearing potential of the potential risk of neural tube defects. Assess the risks and benefits of DOVATO and discuss with the patient to determine if an alternative treatment should be considered at the time of conception through the first trimester of pregnancy or if pregnancy is confirmed in the first trimester
- **Lactation:** Breastfeeding is not recommended due to the potential for HIV-1 transmission, developing viral resistance in HIV-positive infants, and adverse reactions in a breastfed infant
- **Females and Males of Reproductive Potential:** Pregnancy testing is recommended before initiation of DOVATO. Counsel individuals of childbearing potential taking DOVATO on the consistent use of effective contraception
- **Renal Impairment:** DOVATO is not recommended for patients with creatinine clearance <30 mL/min. Patients with a sustained creatinine clearance between 30 and 49 mL/min should be monitored for hematologic toxicities, which may require a dosage adjustment of lamivudine as an individual component
- **Hepatic Impairment:** DOVATO is not recommended in patients with severe hepatic impairment (Child-Pugh Score C)

Please see additional Important Safety Information for DOVATO throughout. Please see accompanying full Prescribing Information. Including Boxed Warning, for DOVATO.

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