SO MUCH GOES INTO WHO YOUR CLIENT IS
HIV MEDICINE IS ONE PART OF IT.

Important Information about DOVATO, a treatment option for your clients.

INDICATION

DOVATO is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults with no antiretroviral treatment history and with no known substitutions associated with resistance to the individual components 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 throughout this brochure. Please click here for full Prescribing Information, including Boxed Warning, for DOVATO.
**WHAT IS DOVATO?**

DOVATO has just 2 medicines in 1 pill and is clinically proven to help your clients reach and then stay undetectable.* That means fewer medicines† in your client’s body today and tomorrow while taking DOVATO.

DOVATO is a once-a-day pill used to treat HIV-1 in treatment-naïve adults.

Results may vary.

*GEMINI-1 & GEMINI-2 studies.

Undetectable means reducing HIV in the blood to very low levels (less than 50 copies per mL).

†As compared with 3-drug regimens.

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**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 if 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

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As a professional working at an AIDS Service Organization (ASO), so much goes into your day. In view of your busy schedule, we’ve created this overview to help you understand information about DOVATO, a treatment option for your clients starting treatment. Because nobody knows your clients—and everything they are—like you do.
CLINICAL STUDIES

DOVATO* was studied in two identically designed, phase 3 double-blind clinical trials (GEMINI-1 and GEMINI-2).†

STUDIED THROUGH 96 WEEKS¹

The studies compared DOVATO to a 3-drug regimen,‡ measuring the percentage of patients with an undetectable§ viral load at 48 weeks (primary endpoint), and 96 weeks to assess the long term effectiveness and safety of DOVATO.

STUDY PARTICIPANTS¹,2

DOVATO was studied in a diverse range of adults. Pooled data from GEMINI-1 & GEMINI-2 studies:

- The median age was 33 years, and 10% were 50 years of age or older
- 31% Hispanic/Latino ethnicity
- 11% Black or African American
- 15% female
- 9% were classified as HIV Stage 3 (AIDS)
- 6% also had hepatitis C virus

Patients who entered this study were treatment-naïve adults (18 years or older) with HIV-1 infection and a screening viral load of 1,000 to ≤500,000 copies/mL. They could not participate if they had hepatitis B infection or preexisting major resistance substitutions/mutations.

STUDY RESULTS

PROVEN TO WORK AT BOTH 48 AND 96 WEEKS

In the GEMINI studies, DOVATO was clinically proven to be as effective at helping people reach and stay undetectable as a regimen‡ containing 3 medicines.

Results may vary.

REACH UNDETECTABLE¹

About 9 out of 10 patients (91%) taking DOVATO reached undetectable at 48 weeks and 86% remained undetectable at 96 weeks.

HOW QUICKLY?³

About 7 out of 10 patients taking DOVATO reached undetectable within 4 weeks.

About 9 out of 10 patients (93%) taking a 3-drug regimen‡ reached undetectable at 48 weeks and 90% remained undetectable at 96 weeks.

About 7 out of 10 patients taking a 3-drug regimen‡ reached undetectable within 4 weeks.

*Subjects were randomized to receive the individual tablets of dolutegravir and lamivudine, administered once daily.
†The trials were double-blind through week 96 and open-label from week 96 to week 148.
‡Dolutegravir + tenofovir disoproxil fumarate/emtricitabine.
§Undetectable means reducing HIV in the blood to less than 50 copies per mL.

IMPORTANT SAFETY INFORMATION (CONT’D)

WARNINGS AND PRECAUTIONS (CONT’D)

Embryo Fetal Toxicity:

- Alternative treatments to DOVATO should be considered at the time of conception through the first trimester of pregnancy due to the risk of neural tube defects
- Perform pregnancy testing before use of DOVATO and counsel that consistent use of effective contraception is recommended while using DOVATO in individuals of childbearing potential

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.

Please see additional Important Safety Information throughout this brochure.

Please click here for full Prescribing Information, including Boxed Warning, for DOVATO.
The most common side effects, reported by ≥2% of patients in either treatment group through 96 weeks, were:

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>DOVATO (%)</th>
<th>A 3-Drug Regimen* (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>3%</td>
<td>4%</td>
</tr>
<tr>
<td>Nausea</td>
<td>2%</td>
<td>5%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>2%</td>
<td>3%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>2%</td>
<td>3%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>Anxiety</td>
<td>2%</td>
<td>1%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>1%</td>
<td>2%</td>
</tr>
</tbody>
</table>

The study medication was discontinued due to adverse events in 3% of patients in both treatment groups. The most common class of adverse events leading to patients stopping DOVATO were psychiatric disorders (1%).

Your clients should always talk to their doctor if they experience any side effects. Results may vary.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Consider chatting with your clients about DOVATO as a treatment option today.

*Dolutegravir + tenofovir disoproxil fumarate/emtricitabine.

IMPORTANT SAFETY INFORMATION (CONT’D)

WARNINGS AND PRECAUTIONS (CONT’D)

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%), and fatigue (2%).
IMPORTANT SAFETY INFORMATION (CONT’D)

DRUG INTERACTIONS

• Consult full Prescribing Information for DOVATO for more information on potentially significant drug interactions
• DOVATO is a complete regimen. 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
• When coadministering DOVATO with carbamazepine or rifampin, take an additional TIVICAY (dolutegravir) 50-mg tablet, approximately 12 hours from the dose of DOVATO
• 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. If planning a pregnancy or if pregnancy is confirmed while taking DOVATO during the first trimester, assess the risks and benefits of continuing DOVATO versus switching to another antiretroviral regimen. For individuals actively trying to become pregnant, initiation of DOVATO is not recommended unless there is no suitable alternative
• 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: Perform pregnancy testing before initiation of DOVATO. Advise individuals of childbearing potential to consistently use effective contraception while taking DOVATO
• Renal Impairment: DOVATO is not recommended for patients with creatinine clearance <50 mL/min

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