

DOVATO.com

## Fewer medicines make DOVATO different.\*

#### What is DOVATO?

DOVATO is a complete prescription regimen for adults new to HIV-1 treatment or replacing their current HIV-1 regimen when their doctor determines they meet certain requirements.

#### **IMPORTANT SAFETY INFORMATION**

#### What is the most important information I should know about DOVATO?

If you have both HIV-1 infection and Hepatitis B virus (HBV) infection, DOVATO can cause serious side effects, including:

• Resistant HBV. Your healthcare provider will test you for HBV infection before you start treatment with DOVATO.

\*As compared with 3- or 4-drug regimens.

Every person featured in this brochure has been compensated by ViiV Healthcare.

Please see Important Safety Information throughout this brochure, including the Important Warnings. Please see Important Facts about DOVATO on page 13.

**Armando** Foodie Switched to DOVATO

"I wanted fewer medicines in my HIV pill, so I talked to my doctor and switched to DOVATO."

**Jovon** Nature Lover Switched to DOVATO

#### Want to stay undetectable\* with fewer medicines?

No other complete HIV pill uses fewer medicines to help keep you undetectable than DOVATO.<sup>†</sup>

\*Undetectable means reducing the HIV in your blood to very low levels (<50 copies per mL). <sup>†</sup>Compared to a tenofovir alafenamide–based 3- or 4-drug regimen.

### What is DOVATO?

DOVATO is a complete prescription regimen to treat HIV-1 in adults who have not received HIV-1 medicines in the past or to replace their current HIV-1 medicines when their doctor determines they meet certain requirements.

#### IMPORTANT SAFETY INFORMATION (cont'd) What is the most important information I should know about DOVATO? (cont'd)

If you have both HIV-1 infection and Hepatitis B virus (HBV) infection, DOVATO can cause serious side effects, including: (cont'd)

If you have HIV-1 and hepatitis B, the HBV can change (mutate) during your treatment with DOVATO and become harder to treat (resistant). It is not known if DOVATO is safe and effective in people who have HIV-1 and HBV infection.

- Worsening of HBV infection. If you have HBV infection and take DOVATO, your HBV may get worse (flare-up) if you stop taking DOVATO. A "flare-up" is when your HBV infection suddenly returns in a worse way than before.
  - Do not run out of DOVATO. Refill your prescription or talk to your healthcare provider before your DOVATO is all gone.
  - Do not stop DOVATO without first talking to your healthcare provider.



#### **DOVATO.com**

"When I found out I had more options, I switched to DOVATO."

> Marnina HIV Activist Switched to DOVATO

### What's the DOVATO difference?

DOVATO is designed differently with just 2 medicines in 1 pill. It's proven to help people reach and stay undetectable\* as effectively as HIV pills that contain 3 or 4 medicines.<sup>†‡</sup>

DOVATO is a one-pill, once-a-day complete treatment for adults who are new to HIV-1 treatment **or** replacing their current HIV-1 medicines. Take DOVATO exactly as your healthcare provider tells you.



## DOVATO is designed differently—with just 2 medicines in 1 pill.

Results may vary.

\*Undetectable means reducing the HIV in your blood to very low levels (<50 copies per mL). †GEMINI-1 & GEMINI-2 studies (patients new to treatment).

<sup>‡</sup>TANGO study (patients replacing their current HIV treatment).

#### **IMPORTANT SAFETY INFORMATION (cont'd)**

## What is the most important information I should know about DOVATO? (cont'd)

#### If you have both HIV-1 infection and Hepatitis B virus (HBV) infection, DOVATO can cause serious side effects, including: (cont'd)

• If you stop taking DOVATO, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your liver function and monitor your HBV infection. It may be necessary to give you a medicine to treat hepatitis B. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking DOVATO.

## For more information about side effects, see "What are the possible side effects of DOVATO?"

#### Who should not take DOVATO?

- Do not take DOVATO if you:
  - have ever had an allergic reaction to a medicine that contains dolutegravir or lamivudine.
  - take dofetilide. Taking DOVATO and dofetilide can cause side effects that may be serious or life-threatening.



#### DOVATO.com



## Why does the DOVATO difference matter?

DOVATO is proven as effective as other single-tablet regimens with fewer medicines in your body—today and tomorrow. Talk to your doctor about whether DOVATO is an HIV treatment that is right for you.

## You could stay undetectable\* with fewer medicines in your body.<sup>†</sup>

\*Undetectable means reducing the HIV in your blood to very low levels (<50 copies per mL). †TANGO study (patients replacing their current HIV treatment).

#### IMPORTANT SAFETY INFORMATION (cont'd) What are other possible side effects of DOVATO?

DOVATO can cause serious side effects, including:

- See "What is the most important information I should know about DOVATO?"
- Allergic reactions. Call your healthcare provider right away if you develop a rash with DOVATO. Stop taking DOVATO and get medical help right away if you develop a rash with any of the following signs or symptoms:
  - fever
  - generally ill feeling
  - tiredness
  - muscle or joint aches
  - blisters or sores in mouth

- blisters or peeling of the skin
- redness or swelling of the eyes
- swelling of the mouth, face, lips, or tongue
- problems breathing



#### **DOVATO.com**

### How do I take DOVATO?



DOVATO is 1 pill taken once a day.

### **DOVATO can be taken:**



Once a day.



Any time of day, around the same time of day.



With or without food.

#### IMPORTANT SAFETY INFORMATION (cont'd)

#### What are other possible side effects of DOVATO? (cont'd)

detect this:

**Fewer medicines\*** 

fit your lifestyle

\*As compared with a 3- or 4-drug regimen.

in an HIV pill could

#### DOVATO can cause serious side effects, including: (cont'd)

• Liver problems. People with a history of hepatitis B or C virus may have an increased risk of developing new or worsening changes in certain liver tests during treatment with DOVATO. Liver problems, including liver failure, have also happened in people without a history of liver disease or other risk factors. Your healthcare provider may do blood tests to check your liver.

#### Tell your healthcare provider right away if you get any of the following signs or symptoms of liver problems:

- your skin or the white part of your eyes turns yellow (jaundice)
- dark or "tea-colored" urine
- light-colored stools (bowel movements)

- nausea or vomiting
- loss of appetite
- pain, aching, or tenderness on the right side of your stomach area



#### **DOVATO.com**

## What does undetectable mean?

Reaching and staying undetectable has always been a key goal of treatment. Simply put, it means taking your HIV treatment as directed can keep the amount of HIV in the blood below the level that can be measured by a lab test.

## What does U=U mean?

### U=U stands for Undetectable equals Untransmittable.

According to the Department of Health & Human Services, people living with HIV who reach and stay undetectable by taking their HIV medication as prescribed prevent transmitting HIV through sex. First, talk to your doctor about further risks of sexual HIV transmission.

#### How long does someone need to be on HIV treatment before the sexual transmission of HIV is prevented?

Achieving an undetectable viral load can take time. Taking HIV treatment as prescribed and getting to and staying undetectable for at least 6 months prevents transmitting HIV through sex. Viral load testing should be performed on a regular basis to confirm HIV remains at an undetectable level.

#### Should I still practice safe sex if I am undetectable?

Regardless of status, condoms can help you lead a healthy sexual life. Unlike HIV treatment, condoms can prevent other sexually transmitted infections (STIs) and pregnancy.

JEU undetectable equals untransmittable

#### IMPORTANT SAFETY INFORMATION (cont'd) What are other possible side effects of DOVATO? (cont'd)

DOVATO can cause serious side effects, including: (cont'd)

• Too much lactic acid in your blood (lactic acidosis). Too much lactic acid is a serious medical emergency that can lead to death.

Tell your healthcare provider right away if you get any of the following symptoms that could be signs of lactic acidosis:

- feel very weak or tired
- unusual (not normal) muscle pain
- trouble breathing
- stomach pain with nausea and vomiting
- feel cold, especially in your arms and legs
- feel dizzy or light-headed
- have a fast or irregular heartbeat



#### **DOVATO.com**

## **Clinical Studies**

## **DOVATO was studied in 3 clinical studies** to determine its effectiveness and safety.

- Two studies included 1,433 adults new to HIV-1 treatment (half started on DOVATO and half started on a 3-drug regimen\*) over a 3-year period
- One additional study included 741 adults who were already undetectable with their previous HIV treatment<sup>†</sup> (approximately half switched to DOVATO, while the other half stayed on their previous treatment) over a 3-year period

## 0 adults who switched to DOVATO developed resistance through 3 years in clinical trials.

Results showed that DOVATO works in a diverse group of adults, regardless of age, sex, race, or CD4 T-cell count.

\*Dolutegravir + tenofovir disoproxil fumarate/emtricitabine. †Tenofovir alafenamide–based 3- or 4-drug regimen.

#### **Across these studies**



#### **DOVATO was clinically proven to control HIV** as effectively as HIV treatments with 3 or 4 medicines by helping people reach and/or stay undetectable.

#### Side Effects

The most common side effects reported in at least 2% of people taking DOVATO include headache, nausea, diarrhea, trouble sleeping, tiredness, and anxiety. These are not the only side effects of DOVATO. Always tell your healthcare provider if you experience any side effect.

## 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.

#### IMPORTANT SAFETY INFORMATION (cont'd) What are other possible side effects of DOVATO? (cont'd)

#### DOVATO can cause serious side effects, including: (cont'd)

- Lactic acidosis can also lead to severe liver problems, which can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). Tell your healthcare provider right away if you get any of the signs or symptoms of liver problems which are listed above under "Liver problems."
- You may be more likely to get lactic acidosis or severe liver problems if you are female or very overweight (obese).
- Changes in your immune system (Immune Reconstitution Syndrome) can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having new symptoms after you start taking DOVATO.

#### **DOVATO.com**



## detect this: talking with your doctor starts with a C.H.A.T.

**C**ommunicate about your life & schedule

ear about treatment options

A sk auestions

alk about your health goals

## Already on treatment and undetectable?

Here are some helpful questions to ask your doctor.

- Does my current HIV treatment have more than 2 medicines?

Could DOVATO be a good option for me to stay undetectable?\* What are the benefits and risks of switching?

- Can DOVATO keep me undetectable?
- How will taking DOVATO fit into my life and daily schedule?

\*Undetectable means reducing the HIV in your blood to very low levels (<50 copies per mL).

#### **IMPORTANT SAFETY INFORMATION (cont'd)** What are other possible side effects of DOVATO? (cont'd)

#### DOVATO can cause serious side effects, including: (cont'd)

- The most common side effects of DOVATO include:
- headache

trouble sleeping

nausea

• tiredness

• diarrhea

anxiety

These are not all the possible side effects of DOVATO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### What should I tell my healthcare provider before taking DOVATO?

#### Before you take DOVATO, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had liver problems, including hepatitis B or C infection.
- have kidney problems.





"I learned that DOVATO had fewer medicines, so I talked to my doctor about switching. It's been great."

#### IMPORTANT SAFETY INFORMATION (cont'd)

#### What should I tell my healthcare provider before taking DOVATO? (cont'd)

#### Before you take DOVATO, tell your healthcare provider about all of your medical conditions, including if you: (cont'd)

- are pregnant or plan to become pregnant. One of the medicines in DOVATO (dolutegravir) may harm your unborn baby.
  - Your healthcare provider may prescribe a different medicine than DOVATO if you are planning to become pregnant or if pregnancy is confirmed during the first 12 weeks of pregnancy.
  - If you can become pregnant, your healthcare provider may perform a pregnancy test before you start treatment with DOVATO.
  - If you can become pregnant, you and your healthcare provider should talk about the use of effective birth control (contraception) during treatment with DOVATO.
  - Tell your healthcare provider right away if you are planning to become pregnant, you become pregnant, or think you may be pregnant during treatment with DOVATO.

#### **DOVATO.com**

Please see Important Safety Information throughout this brochure, including the Important Warnings. Please see Important Facts about DOVATO on page 13.



Ann

& Author Switched to DOVATO

**Retired Educator** 

"After I switched to DOVATO, I stayed undetectable with fewer medicines. I was so happy!"

#### Robin

**Community Health** Educator Switched to DOVATO

### **New to treatment?**

#### Here are some helpful questions to ask your doctor.

- Could DOVATO be a good option for me to control my HIV?
- What are the benefits and risks?
- **2** How many medicines are in each treatment option?
- Can I reach and then stay undetectable\* with DOVATO?
- How will taking DOVATO fit into my life and daily schedule?

\*Undetectable means reducing the HIV in your blood to very low levels (<50 copies per mL).

### **IMPORTANT SAFETY INFORMATION (cont'd)**

#### What should I tell my healthcare provider before taking DOVATO? (cont'd)

#### Before you take DOVATO, tell your healthcare provider about all of your medical conditions, including if you: (cont'd)

- are breastfeeding or plan to breastfeed. **Do not breastfeed if you** take DOVATO.
  - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
  - DOVATO passes to your baby in your breast milk.
  - Talk with your healthcare provider about the best way to feed your baby.









# Hear stories from real ambassadors about switching to DOVATO.

Visit us at <u>DOVATO.com/real-stories/</u>

#### IMPORTANT SAFETY INFORMATION (cont'd) What should I tell my healthcare provider before taking DOVATO? (cont'd)

#### Tell your healthcare provider about all the medicines you take,

including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medicines interact with DOVATO. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with DOVATO.
- Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take DOVATO with other medicines.



#### **DOVATO.com**

"Over the years, I've gone from multiple HIV pills a day to 1."

## Is the DOVATO difference right for you?

Talk to your doctor about switching to DOVATO.

### **DOVATO.com**

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.

Please read the Patient Information for DOVATO and discuss it with your healthcare provider.

Please see Important Safety Information throughout this brochure, including the Important Warnings. Please see Important Facts about DOVATO on page 13.



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Morgan Avid Traveler Switched to DOVATO

Check out ways to access your prescribed ViiV Healthcare medications

Insurance Review

Financial Assistance Programs<sup>a</sup>

Call to speak to an Access Coordinator





LEARN MORE

Monday-Friday, 8AM-11PM (ET)

<sup>a</sup>Subject to eligibility and program terms and conditions; ViiVConnect programs do not constitute health insurance.



### **IMPORTANT FACTS**

This is only a brief summary of important information about DOVATO and does not replace talking to your healthcare provider about your condition and treatment.

#### (doe VAH toe)

#### **MOST IMPORTANT INFORMATION ABOUT DOVATO**

If you have both human immunodeficiency virus-1 (HIV-1) infection and Hepatitis B virus (HBV) infection, DOVATO can cause serious side effects, including:

- Resistant HBV. Your healthcare provider will test you for HBV infection before you start treatment with DOVATO. If you have HIV-1 and hepatitis B, the HBV can change (mutate) during your treatment with DOVATO and become harder to treat (resistant). It is not known if DOVATO is safe and effective in people who have HIV-1 and HBV infection.
- Worsening of HBV infection. If you have HBV infection and take DOVATO, your HBV may get worse (flare-up) if you stop taking DOVATO. A "flare-up" is when your HBV infection suddenly returns in a worse way than before.
  - Do not run out of DOVATO. Refill your prescription or talk to your healthcare provider before your DOVATO is all gone.
  - Do not stop DOVATO without first talking to your healthcare provider.
  - If you stop taking DOVATO, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your liver function and monitor your HBV infection. It may be necessary to give you a medicine to treat hepatitis B. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking DOVATO.

## For more information about side effects, see "POSSIBLE SIDE EFFECTS OF DOVATO".

#### **ABOUT DOVATO**

- DOVATO is a prescription medicine that is used without other HIV-1 medicines to treat HIV-1 infection in adults:
  - who have not received HIV-1 medicines in the past, or
  - to replace their current HIV-1 medicines when their healthcare provider determines that they meet certain requirements.

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS). It is not known if DOVATO is safe and effective in children.

#### **DO NOT TAKE DOVATO IF YOU**

- have ever had an allergic reaction to a medicine that contains dolutegravir or lamivudine.
- take dofetilide. Taking DOVATO and dofetilide can cause side effects that may be serious or life-threatening.

#### **BEFORE TAKING DOVATO**

## Tell your healthcare provider about all of your medical conditions, including if you:

- have or have had liver problems, including hepatitis B or C infection.
- have kidney problems.
- are pregnant or plan to become pregnant. One of the medicines in DOVATO (dolutegravir) may harm your unborn baby.
  - Your healthcare provider may prescribe a different medicine than DOVATO if you are planning to become pregnant or if pregnancy is confirmed during the first 12 weeks of pregnancy.
  - If you can become pregnant, your healthcare provider may perform a pregnancy test before you start treatment with DOVATO.
  - If you can become pregnant, you and your healthcare provider should talk about the use of effective birth control (contraception) during treatment with DOVATO.
  - Tell your healthcare provider right away if you are planning to become pregnant, you become pregnant, or think you may be pregnant during treatment with DOVATO.
- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take DOVATO.**
- You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
  - DOVATO passes to your baby in your breast milk.
- Talk with your healthcare provider about the best way to feed your baby.
   Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

#### BEFORE TAKING DOVATO (CONT'D)

Some medicines interact with DOVATO. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with DOVATO.
- Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take DOVATO with other medicines.

#### POSSIBLE SIDE EFFECTS OF DOVATO

DOVATO can cause serious side effects, including:

- See "MOST IMPORTANT INFORMATION ABOUT DOVATO".
- Allergic reactions. Call your healthcare provider right away if you develop a rash with DOVATO. Stop taking DOVATO and get medical help right away if you develop a rash with any of the following signs or symptoms: fever; generally ill feeling; tiredness; muscle or joint aches; blisters or sores in mouth; blisters or peeling of the skin; redness or swelling of the eyes; swelling of the mouth, face, lips, or tongue; problems breathing.
- Liver problems. People with a history of hepatitis B or C virus may have an increased risk of developing new or worsening changes in certain liver tests during treatment with DOVATO. Liver problems, including liver failure, have also happened in people without a history of liver disease or other risk factors. Your healthcare provider may do blood tests to check your liver.

Tell your healthcare provider right away if you get any of the following signs or symptoms of liver problems: your skin or the white part of your eyes turns yellow (jaundice); dark or "tea-colored" urine; light-colored stools (bowel movements); nausea or vomiting; loss of appetite; and/or pain, aching, or tenderness on the right side of your stomach area.

- Too much lactic acid in your blood (lactic acidosis). Too much lactic acid is a serious medical emergency that can lead to death. Tell your healthcare provider right away if you get any of the following symptoms that could be signs of lactic acidosis: feel very weak or tired; unusual (not normal) muscle pain; trouble breathing; stomach pain with nausea and vomiting; feel cold, especially in your arms and legs; feel dizzy or lightheaded; and/or a fast or irregular heartbeat.
- Lactic acidosis can also lead to severe liver problems, which can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). Tell your healthcare provider right away if you get any of the signs or symptoms of liver problems which are listed above under "Liver problems."
- You may be more likely to get lactic acidosis or severe liver problems if you are female or very overweight (obese).
- Changes in your immune system (Immune Reconstitution Syndrome) can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having new symptoms after you start taking DOVATO.
- The most common side effects of DOVATO include: headache; nausea; diarrhea; trouble sleeping; tiredness; and anxiety.

These are not all the possible side effects of DOVATO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### **GET MORE INFORMATION**

- Talk to your healthcare provider or pharmacist.
  Go to DOVATO com or call 1-877-844-8872
- Go to DOVATO.com or call 1-877-844-8872, where you can also get FDA-approved labeling.

#### October 2022 DVT:10PI-7PIL

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DLLBR0C220005 November 2022 Produced in USA.