

Dovato
dolutegravir 50 mg/
lamivudine 300 mg tablets

DOVATO.com

SO MUCH GOES INTO WHO I AM

HIV MEDICINE SHOULD BE THE LEAST OF IT.

What is DOVATO?

DOVATO is a prescription medicine that is used without other antiretroviral medicines to treat human immunodeficiency virus-1 (HIV-1) infection in adults who have not received antiretroviral medicines in the past, **and** without known resistance to the medicines dolutegravir or lamivudine.

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

IMPORTANT SAFETY INFORMATION

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

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

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

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

Please see Important Safety Information throughout this brochure, including an important warning on worsening of hepatitis B infection. Please see Important Facts about DOVATO on page 12.



DISCOVER DOVATO



A complete treatment

DOVATO has just **2 medicines in 1 pill** and is clinically proven to help you reach and then stay undetectable.* That means fewer medicines[†] in your body, today and tomorrow, while taking DOVATO.

DOVATO is a once-a-day complete treatment for adults who are new to HIV-1 medicine.

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.

IMPORTANT SAFETY INFORMATION (cont'd)

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

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

If you have HIV-1 and hepatitis B, the hepatitis B virus 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 HIV-1 and HBV infection, your HBV may get worse (flare-up) if you stop taking DOVATO.

Please see Important Safety Information throughout this brochure, including an important warning on worsening of hepatitis B infection. Please see Important Facts about DOVATO on page 12.

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ALPHONSO

Living with HIV

HELPFUL TIP

Always be honest about your schedule and needs with your doctor. They can help you find a treatment that will fit into your life.

**My life...it's filled with my son,
road trips, and mentoring!
I am looking forward
to more to come.**

— Leo
Living with HIV

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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

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LEO

Living with HIV

HELPFUL TIP

Your healthcare team is there to help you. Let your healthcare provider know how you feel, and together you can create a plan to help you live healthy with HIV.

I love going to the gym
and lifting weights.
I find when I pick up heavy things
the rest of the world seems lighter.

— **Kalvin**
Living with HIV

KALVIN

Living with HIV

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

HELPFUL TIP

Taking your medicine every day as prescribed can become part of your daily routine and start to feel like second nature.

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COULD FEWER MEDICINES IN YOUR HIV TREATMENT BE RIGHT FOR YOU?

CHAT with your doctor to find out.

Communicate about your life & schedule

Hear about treatment options

Ask questions

Talk about your health goals

DISCUSSING DOVATO

Ask your doctor these questions.

- 1.** Why could DOVATO be a good option for me to control my HIV? What are the benefits and risks?
- 2.** Can I reach and then stay undetectable with DOVATO?
- 3.** How will taking DOVATO fit into my life and daily schedule?

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).**

IMPORTANT SAFETY INFORMATION (cont'd)

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

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

- **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.

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WHAT DO THE STUDIES SAY?

In 2 recent studies, DOVATO was clinically proven to help people reach undetectable.*

Reach undetectable

About 9 out of 10 patients taking DOVATO reached undetectable at 48 weeks.

About 9 out of 10 patients taking a 3-drug regimen† reached undetectable at 48 weeks.

How quickly?

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

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

Side effects

Across the combined GEMINI studies, 18% of patients taking DOVATO versus 24% taking a 3-drug regimen† experienced side effects.

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).

†Dolutegravir + tenofovir disoproxil fumarate/emtricitabine.

The most common side effects for patients taking DOVATO were headache, diarrhea, nausea, trouble sleeping, and tiredness.

Please see Important Safety Information throughout this brochure, including an important warning on worsening of hepatitis B infection. Please see Important Facts about DOVATO on page 12.

The most common side effects through 48 weeks, reported by 2% or more of patients in either treatment group, were:

	DOVATO	A 3-Drug Regimen†
Headache	3%	4%
Nausea	2%	5%
Diarrhea	2%	3%
Trouble sleeping	2%	3%
Tiredness	2%	2%
Dizziness	1%	2%

Your results may vary.

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)

- The most common side effects of DOVATO include:
 - headache
 - diarrhea
 - nausea
 - trouble sleeping
 - tiredness

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.

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**I am not letting my status
take away my *umph* to live...
I don't want to live life with
coulda, shoulda, woulda.**

— LáDeia
Living with HIV

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.

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.

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Please see Important Safety Information throughout this brochure, including an important warning on worsening of hepatitis B infection. Please see Important Facts about DOVATO on page 12.

LáDEIA

Living with HIV

HELPFUL TIP

Stay true to you. Work with your doctor to find the right treatment plan for you, one that helps you meet your health goals and fits into your life.

LEARN MORE ABOUT DOVATO

DOVATO.com

Please see Important Facts about DOVATO on page 12.



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 **ViiVConnect**

For information on access and coverage to help
you get your prescribed ViiV Healthcare medications
Insured • Underinsured • Uninsured

[LEARN MORE](#)



1-844-588-3288 (toll free)
Monday-Friday, 8AM-11PM (ET)



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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) and hepatitis B virus (HBV) infection, DOVATO can cause serious side effects, including:

- **Resistant HBV infection.** Your healthcare provider will test you for HBV infection before you start treatment with DOVATO. If you have HIV-1 and hepatitis B, the hepatitis B virus 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 HIV-1 and HBV infection, 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. Worsening liver disease can be serious and may lead to death.
 - 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.

ABOUT DOVATO

- DOVATO is a prescription medicine that is used without other antiretroviral medicines to treat HIV-1 infection in adults:
 - who have not received antiretroviral medicines in the past, **and**
 - without known resistance to the medicines dolutegravir or lamivudine.
- 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.

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.
 - **You should not take DOVATO if you are planning to become pregnant or during the first 12 weeks of pregnancy.** Your healthcare provider may prescribe a different medicine if you are planning to become pregnant or become pregnant during treatment with DOVATO.
 - If you can become pregnant, your healthcare provider will perform a pregnancy test before you start treatment with DOVATO.
 - If you can become pregnant, you should consistently use 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.
 - One of the medicines in DOVATO (lamivudine) passes into your breastmilk.
 - 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:

- Those in the “Most Important information about DOVATO” section.
- **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).** Lactic acidosis 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; diarrhea; nausea; trouble sleeping; and tiredness.

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, where you can also get FDA-approved labeling.

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