Delstrigo

doravirine/lamivudine/ tenofovir disoproxil fumarate 100 mg/300 mg/300 mg tablets

When life brings change, what inspires the?

WHAT IS DELSTRIGO?

DELSTRIGO is a complete, one-pill prescription HIV medicine used 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 for people whose healthcare provider determines that they meet certain requirements. HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).

IV-positive model

IMPORTANT SAFETY INFORMATION Worsening of hepatitis B virus infection (HBV).

If you have both Human Immunodeficiency Virus-1 (HIV-1) and HBV and stop taking DELSTRIGO, your HBV may suddenly get worse. Do not stop taking DELSTRIGO without first talking to your healthcare provider, as they will need to monitor your health. Your healthcare provider should test you for HBV infection before you start treatment with DELSTRIGO.

READY FOR CHANGE

hen our lives change, we can change too. By finding fresh inspiration in the people around us. New joy in the things that complete us. And new choices in the treatments available to us. If you are considering your HIV-1 treatment options, it may be time to learn about DELSTRIGO.

LIFE CHANGES. STAY INSPIRED.

DHHS TREATMENT GUIDELINES

Department of Health and Human Services (DHHS) guidelines support changing HIV-1 treatment regimens for several reasons, including:



Food requirements



Potential interactions with other drugs

Side effects

TABLE OF CONTENTS

TAKING DELSTRIGO	3
OTHER MEDICATIONS	4
YOUR HEALTH AND HIV-1	5
STUDY RESULTS	5
SIDE EFFECTS	6
ABOUT CHOLESTEROL	7
QUESTIONS FOR YOUR DOCTOR	8

IMPORTANT SAFETY INFORMATION (continued)

Do not take DELSTRIGO if you are currently taking any of the following medicines:

- carbamazepine
- oxcarbazepine
- phenobarbital
- phenytoin
- enzalutamide
- rifampin
- rifapentine
- mitotane
- St. John's wort

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. If you have taken any of the medicines in the past 4 weeks, talk to your healthcare provider or pharmacist before starting DELSTRIGO.

ARE YOU READY FOR A CHANGE? ASK YOUR DOCTOR IF *DELSTRIGO* IS RIGHT FOR YOU.



TAKING DELSTRIGO

Some life changes can be an opportunity to form new habits. You and your healthcare provider can decide if DELSTRIGO could be right for you.



DELSTRIGO is 1 pill for HIV-1 usually taken by itself (without other HIV medicines)



Take DELSTRIGO **1 time each day**, about the same time every day



DELSTRIGO can be taken with or without food

IMPORTANT SAFETY INFORMATION (continued)

Take DELSTRIGO every day exactly as your healthcare provider tells you to take it.

If you take the medicine rifabutin during treatment with DELSTRIGO, your healthcare provider will also prescribe an additional dose of doravirine for you. Carefully follow your healthcare provider's instruction about when to take doravirine and how much to take. This is usually 1 tablet of doravirine about 12 hours after your last dose of DELSTRIGO. Do not change your dose or stop taking DELSTRIGO without talking to your healthcare provider first.

Take DELSTRIGO on a regular dosing schedule as instructed by your healthcare provider. Do not miss doses.



IMPORTANT SAFETY INFORMATION (continued)

Get your DELSTRIGO refilled from your healthcare provider or pharmacy before you run out.

Do not take DELSTRIGO if you have ever had an allergic reaction to lamivudine.

New or worse kidney problems, including kidney failure, can happen while you are taking DELSTRIGO. Your healthcare provider should do blood and urine tests to check your kidneys. If you develop new or worse kidney problems, your healthcare provider may tell you to stop taking DELSTRIGO.



DELSTRIGO AND OTHER MEDICATIONS

Getting to and staying undetectable is extremely important, and it's also important to consider whether your HIV-1 treatment can be used with other medicines.

DELSTRIGO may be taken with a wide range of non–HIV-1 medications for the following common conditions:



CHOLESTEROL STATINS (atorvastatin)



DIABETES

METFORMIN (metformin hydrochloride)



HEARTBURN PROTON PUMP INHIBITORS (pantoprazole)



POSSIBILITY OF PREGNANCY

ORAL CONTRACEPTIVES (ethinyl estradiol and levonorgestrel)



PAIN METHADONE

DELSTRIGO should be avoided with concurrent or recent use of a nephrotoxic agent (eg, highdose or multiple nonsteroidal anti-inflammatory drugs [NSAIDs]).

IMPORTANT SAFETY INFORMATION (continued)

Some people who take DELSTRIGO experience bone problems such as pain, softening, or thinning of the bone. Tell your healthcare provider if you have any of the following symptoms during treatment with DELSTRIGO: bone pain that does not go away or worsening bone pain; pain in your arms, legs, hands or feet; broken bones; or muscle pain or weakness.



Some medicines interact with DELSTRIGO.

Before starting DELSTRIGO, tell your doctor if you have ever had an allergic reaction to lamivudine, or if you are taking any of the following medicines: carbamazepine, oxcarbazepine, phenobarbital, phenytoin, enzalutamide, rifampin, rifapentine, mitotane, or St. John's wort.

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

When talking to your doctor about treatment options, be sure to tell them about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

IMPORTANT SAFETY INFORMATION (continued)

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 starting your HIV-1 medicine.

> Delstrigo[•] doravirine/lamivudine/ tenofovir disoproxil fumarate 100 mg/300 mg/300 mg tablets

YOUR HEALTH AND HIV-1

DELSTRIGO can help you get your viral load to undetectable. Undetectable means the level of HIV in your blood is so low that lab tests can't detect it. And when your HIV is under control, you can focus on your health and life goals beyond HIV.

STAYING UNDETECTABLE IS IMPORTANT

In a 48-week study, adults living with HIV-1 who were undetectable on their current treatment regimen switched to **DELSTRIGO** either at the start of the study, or at Week 24 of the study.

IMPORTANT SAFETY INFORMATION (continued)

The most common side effects of DELSTRIGO include: dizziness, nausea, and abnormal dreams.

These are not all the possible side effects of DELSTRIGO. For more information, ask your healthcare provider or pharmacist.



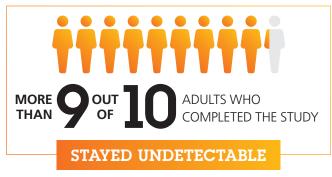
AT THE START OF THE STUDY:

- 447 adults switched to DELSTRIGO
- **91%** of those adults stayed undetectable at Week 48

AT WEEK 24 OF THE STUDY:

- 209 adults switched to DELSTRIGO
- **95%** of those adults were undetectable at Week 24 before switching to DELSTRIGO
- 95% stayed undetectable at Week 48

AT WEEK 48 OF THE STUDY:



DELSTRIGO may not have these effects on all adults living with HIV.

MORE ABOUT THIS STUDY

Patients were undetectable (HIV-1 RNA <50 copies/mL) for at least 6 months before starting the trial and had no history of resistance* to DELSTRIGO.

Before switching to DELSTRIGO, patients were taking one of the following treatment regimen options:

- 2 NRTIs in combination with a PI plus either ritonavir or cobicistat, or elvitegravir plus cobicistat, or
- An NNRTI

Patients were assigned by chance to one of the two treatment groups in the study. Patients and their healthcare providers taking part in the study knew which group they were part of.

*Resistance happens when the virus mutates and your medicine stops working.

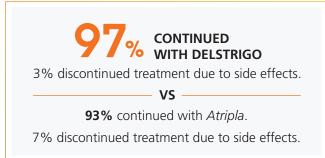




A LOW RATE OF SIDE EFFECTS

In a 96-week study of adults who had never been on an HIV-1 treatment before, 364 adults received **DELSTRIGO** while 364 adults received an *Atripla* (EFV/FTC/TDF) once-daily tablet.

Fewer adults stopped taking DELSTRIGO than *Atripla* because of side effects.



In this study, the most common side effects of DELSTRIGO were dizziness **7%**, nausea **5%**, and abnormal dreams **5%**.

LIFE CHANGES. STAY INSPIRED.

IMPORTANT SAFETY INFORMATION (continued)

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 starting your HIV-1 medicine.

IMPORTANT SAFETY INFORMATION (continued)

The most common side effects of DELSTRIGO include: dizziness, nausea, and abnormal dreams.

These are not all the possible side effects of DELSTRIGO. For more information, ask your healthcare provider or pharmacist.



6

ABOUT CHOLESTEROL

HIV may have a negative effect on your bad cholesterol (LDL-C).

In a 96-week study of adults who were new to treatment, 320 adults received DELSTRIGO and 307 adults received *Atripla*.

DELSTRIGO did not increase bad cholesterol, while *Atripla* did.

EFFECT ON BAD CHOLESTEROL (LDL-C) AT WEEK 48:



The benefit of these changes has not been demonstrated.

IMPORTANT SAFETY INFORMATION (continued)

Before starting DELSTRIGO, tell your healthcare provider about all your medical conditions, including if you have hepatitis B virus infection; kidney problems; bone problems, including a history of bone fractures; are pregnant or plan to become pregnant; or are breastfeeding or plan to breastfeed. It is not known if DELSTRIGO can harm your unborn baby. Do not breastfeed if you take DELSTRIGO. Women with HIV should not breastfeed because their babies could be infected with HIV through their breast milk.



STARTING THE CONVERSATION

Only you and your doctor know what treatment is right for you. Here are some questions you can use to start a conversation about your treatment options.



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How will my treatment fit into my routine?



What side effects could I experience?

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Could my HIV-1 treatment impact my weight?

Can my HIV-1 treatment have a negative effect on my cholesterol?

Can I still take other medications with my HIV-1 medication?

Do I need to eat when I take my HIV-1 medication?



Are there other health risks my HIV or HIV-1 treatment could cause?

TAKE A PIC OF THESE QUESTIONS AND DISCUSS WITH YOUR DOCTOR.

AN ADDITIONAL TREATMENT CONSIDERATION

Maintaining a healthy weight is an important part of taking care of your health and managing your HIV. You may have concerns about weight change. If you do, talk to your doctor.

IMPORTANT SAFETY INFORMATION (continued)

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 DELSTRIGO. Keep a list of your medicines to show your healthcare provider and pharmacist. Tell your healthcare provider if you have taken rifabutin in the past 4 weeks. Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take DELSTRIGO with those other medicines.





LIFE CHANGES. STAY CONNECTED.

ASK YOUR DOCTOR IF **DELSTRIGO IS RIGHT** FOR YOU.

READY TO LEARN MORE ABOUT DELSTRIGO?



Scan this code and find out if **DELSTRIGO** is right for you

Delstrigo doravirine/lamivudine/ tenofovir disoproxil fumarate 100 mg/300 mg/300 mg tablets



FREE TRIAL OFFER FOR DELSTRIGO

Eligible patients may receive a 30-tablet trial supply of DELSTRIGO



Scan the QR code to learn about a Free Trial Offer for DELSTRIGO.

Not all patients are eligible. Certain restrictions apply. Please see Terms and Conditions.



Visit delstrigo.com/freetrial to determine if you are eligible for the Free Trial Offer for DELSTRIGO.



Save the voucher to your mobile device or print it.



Present the voucher with a valid signed prescription to any participating eligible retail pharmacy (certain restrictions apply).

There is no requirement to purchase any product or service for you to receive a free 30-tablet trial supply of DELSTRIGO. Not all patients are eligible. Certain restrictions apply. See Terms and Conditions.

Please read the accompanying <u>Patient Information</u> for DELSTRIGO, including an important warning about the potential worsening of hepatitis B after stopping DELSTRIGO, and discuss it with your healthcare provider. The physician <u>Prescribing Information</u> also is available.



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