

# MOVING FORWARD with TRIUMEQ.

Important information for  
you and your clients to  
consider about TRIUMEQ

**Jack**  
Diagnosed with HIV in 2010



**Juan**  
Supporting Jack since 2011

**ASO  
PRO**

Real patient with HIV-1 taking TRIUMEQ as of 2014 or later.  
Individual results may vary.

Individuals compensated for their time by ViiV Healthcare.

**ASO=AIDS Service Organization**

## INDICATIONS AND USAGE

TRIUMEQ is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and in pediatric patients weighing at least 40 kg.

### Limitations of Use:

TRIUMEQ alone is not recommended in patients with resistance-associated integrase substitutions or clinically suspected integrase strand transfer inhibitor (INSTI) resistance because the dose of dolutegravir in TRIUMEQ is insufficient in these subpopulations. See full prescribing information for TIVICAY.

## IMPORTANT SAFETY INFORMATION

### BOXED WARNING: HYPERSENSITIVITY REACTIONS AND EXACERBATIONS OF HEPATITIS B VIRUS (HBV)

#### Hypersensitivity Reactions:

- Serious and sometimes fatal hypersensitivity reactions, with multiple organ involvement, have occurred with abacavir-containing products

- Patients who carry the HLA-B\*5701 allele are at a higher risk of experiencing a hypersensitivity reaction to abacavir, although hypersensitivity reactions have occurred in patients who do not carry the HLA-B\*5701 allele
- TRIUMEQ is contraindicated in patients with a prior hypersensitivity reaction to abacavir and in HLA-B\*5701-positive patients. All patients should be screened for the HLA-B\*5701 allele prior to initiating therapy or reinitiation of therapy with TRIUMEQ unless patients have a previously documented HLA-B\*5701 allele assessment

- Discontinue TRIUMEQ as soon as hypersensitivity reaction is suspected. Regardless of HLA-B\*5701 status, permanently discontinue TRIUMEQ if hypersensitivity cannot be ruled out, even when other diagnoses are possible
- Following a hypersensitivity reaction to TRIUMEQ, NEVER restart TRIUMEQ or any other abacavir-containing product

Boxed Warning cont'd on page 2

Please see Important Safety Information throughout this brochure.  
Please click [here](#) to see full Prescribing Information, including Boxed Warning and Medication Guide.

 **Triumeq**  
abacavir 600 mg/dolutegravir 50 mg/  
lamivudine 300 mg tablets



# People with HIV look to **YOU** for direction.

## Moving forward can start today

As an ASO professional, you help your clients overcome challenges, day in and day out. Whether those clients are new to treatment or ready to explore another treatment option, this brochure includes helpful information about why they might want to consider asking their healthcare professional about TRIUMEQ.

572 Trl

### TRIUMEQ is one pill, taken once a day

TRIUMEQ is a once-a-day prescription medicine used to treat HIV-1. TRIUMEQ should not be used by itself in some people and should be taken exactly as your clients' healthcare providers have prescribed.

- ▶ Instruct clients to read the Medication Guide before starting TRIUMEQ and to reread it each time the prescription is refilled. Instruct clients to inform their healthcare provider or pharmacist if they develop any unusual symptom, or if any known symptom persists or worsens.



Jeannette  
Diagnosed with HIV in 2011



Real patient with HIV-1 taking TRIUMEQ as of 2014 or later. Individual results may vary. Individual compensated for her time by Viiv Healthcare.

## IMPORTANT SAFETY INFORMATION (cont'd)

### BOXED WARNING: HYPERSENSITIVITY REACTIONS AND EXACERBATIONS OF HEPATITIS B VIRUS (HBV) (cont'd)

#### Exacerbations of Hepatitis B:

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

### CONTRAINDICATIONS

- Do not use TRIUMEQ in patients who have the HLA-B\*5701 allele
- Do not use TRIUMEQ in patients with previous hypersensitivity reaction to abacavir, dolutegravir, or lamivudine
- Do not use TRIUMEQ in patients receiving dofetilide
- Do not use TRIUMEQ in patients with moderate or severe hepatic impairment

### 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

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# Why shouldn't that direction be **FORWARD?**

**TRIUMEQ is a recommended treatment option by the Department of Health and Human Services (DHHS) for patients who have not previously taken HIV medication.<sup>1\*</sup>**

\*DHHS HIV Treatment Guidelines recommend the use of certain integrase strand transfer inhibitor (INSTI)-based regimens as initial treatment for most people with HIV. TRIUMEQ is one of several regimens recommended by DHHS and should only be used in patients who are HLA-B\*5701 negative.

TRIUMEQ is not a cure for HIV-1 infection, and clients may continue to experience illnesses associated with HIV-1 infection, including opportunistic infections. Clients must remain on continuous HIV therapy to control HIV-1 infection and decrease HIV-related illness.

**Peter**

Diagnosed with HIV in 2015

Real patient with HIV-1 taking TRIUMEQ as of 2014 or later. Individual results may vary.

Individual compensated for his time by ViiV Healthcare.

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

### **WARNINGS AND PRECAUTIONS (cont'd)**

#### **Hypersensitivity Reactions: (cont'd)**

- Clinically, it is not possible to determine whether a hypersensitivity reaction with TRIUMEQ would be caused by abacavir or dolutegravir
- Discontinue TRIUMEQ immediately if signs or symptoms of 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

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## Learn more about TRIUMEQ

With the challenges your clients may face when it comes to factors like when and how they take their medication, it may be helpful to discuss with them 4 things about TRIUMEQ that might be important to them.

# 4 things to know:



### TRIUMEQ can help you get to and maintain an undetectable viral load<sup>2,3</sup>

Undetectable means less than 50 copies of HIV-1 RNA in a milliliter of blood. Results may vary.



### TRIUMEQ is one pill, taken once a day

TRIUMEQ is not for use by itself in some people. Tell your clients to take TRIUMEQ exactly as their healthcare provider tells them.



### It can be taken day or night, around the same time each day



### It can be taken with or without food

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

#### Hepatotoxicity: (cont'd)

- 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 TRIUMEQ. 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
- Drug-induced liver injury leading to liver transplant has been reported with TRIUMEQ
- Monitoring for hepatotoxicity is recommended

#### Lactic Acidosis and Severe Hepatomegaly with Steatosis:

Fatal cases have been reported with the use of nucleoside analogues, including abacavir and lamivudine. Discontinue TRIUMEQ if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

#### Embryofetal Toxicity:

- Alternative treatments to TRIUMEQ 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 TRIUMEQ and counsel that consistent use of effective contraception is recommended while using TRIUMEQ in adolescents and adults of childbearing potential.

**Adverse Reactions or Loss of Virologic Response Due to Drug Interactions** with concomitant use of TRIUMEQ 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 TRIUMEQ.

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## The HLA-B\*5701 Screening Test<sup>1</sup>

In addition to blood tests to check your clients' HIV, there are also other tests to see if certain HIV-1 medicines are an option for them. One of these tests is the HLA-B\*5701 screening test.

Ask your clients to check with their healthcare provider and see if they have had an HLA-B\*5701 screening test. If they haven't, make sure to recommend that they request it.

### If your client's HLA-B\*5701 test is POSITIVE:

- ▶ Your client has the HLA-B\*5701 gene variation.
- ▶ This means your client should not take medicines containing abacavir, including TRIUMEQ.
- ▶ Your client has a much higher risk for a serious allergic reaction (hypersensitivity reaction) that can cause death if they take medicines containing abacavir, including TRIUMEQ.

### If your client's HLA-B\*5701 test is NEGATIVE:

- ▶ Your client does not have the HLA-B\*5701 gene variation.
- ▶ Your client may still have a hypersensitivity reaction to TRIUMEQ, though the risk is much lower.
- ▶ Ask your client to check with their healthcare provider to determine if a medicine containing abacavir, like TRIUMEQ, may be right for them.

## IMPORTANT SAFETY INFORMATION (cont'd) WARNINGS AND PRECAUTIONS (cont'd)

### Myocardial Infarction (MI):

- Several observational studies have reported an association with the use of abacavir and the risk of MI; meta-analyses of randomized controlled clinical trials did not show increased risk. To date, there is no established biological mechanism to explain a potential increase in risk. In totality, the available data show inconsistency; therefore, evidence for a causal relationship between abacavir and the risk of MI is inconclusive

- The underlying risk of coronary heart disease should be considered when prescribing antiretroviral therapies, including abacavir, and action taken to minimize all modifiable risk factors (eg, hypertension, hyperlipidemia, diabetes mellitus, smoking)

### ADVERSE REACTIONS

The most common adverse reactions (incidence  $\geq 2\%$ , Grades 2-4) in treatment-naïve adults receiving TRIUMEQ were insomnia (3%), headache (2%), and fatigue (2%).

### Garland

Diagnosed with HIV in 2016

Real patient with HIV-1 taking TRIUMEQ as of 2014 or later. Individual results may vary.

Individual compensated for his time by ViiV Healthcare.

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## Clinical information for a study of TRIUMEQ at 144 weeks

### A look at the SINGLE study<sup>2,4</sup>

- ▶ SINGLE was a randomized, double-blind (to Week 96; open-label\* from Week 96 to Week 144), active-control trial in HLA-B\*5701-negative adults with HIV-1 who had not started an HIV-1 treatment before.
- ▶ SINGLE compared the efficacy and safety of 2 HIV-1 treatment regimens: TRIUMEQ once daily (n=414) vs Atripla® once daily (n=419) in 833 patients at 48 weeks (primary endpoint), 96 weeks, and 144 weeks.
- ▶ At baseline, the median age of patients was 35 years, 16% were female, 32% were nonwhite, 7% had hepatitis C virus co-infection (patients with hepatitis B virus were excluded from this study), 4% were CDC Class C (AIDS), 32% had HIV-1 RNA >100,000 copies/mL, and 53% had CD4<sup>+</sup> T-cell counts <350 cells/mm<sup>3</sup>.

\*In an open-label trial, both the patient and healthcare provider know the treatment regimen the patient is receiving.

CDC=Centers for Disease Control and Prevention.  
CI=confidence interval.

### RESULTS AT 144 WEEKS (ABOUT 3 YEARS):<sup>2,4</sup>

	TRIUMEQ	ATRIPLA
<b>UNDETECTABLE VIRAL LOAD</b>	71% of patients who took <b>TRIUMEQ</b> had a viral load of HIV-1 RNA <50 copies/mL.	63% of patients who took <b>Atripla</b> had a viral load of HIV-1 RNA <50 copies/mL.
The treatment difference in response was statistically superior: 8.3% (95% CI; 2.0%, 14.6%) for the Week 144 snapshot analysis.		
<b>INCREASE IN CD4 CELL COUNTS<sup>†</sup></b>	378 cells/mm <sup>3</sup> was the average increase in CD4 cell count in patients who took <b>TRIUMEQ</b> .	332 cells/mm <sup>3</sup> was the average increase in CD4 cell count in patients who took <b>Atripla</b> .
<b>STOPPED TREATMENT DUE TO SIDE EFFECTS</b>	4% of patients stopped taking <b>TRIUMEQ</b> due to side effects.	14% of patients stopped taking <b>Atripla</b> due to side effects.

The difference in virologic efficacy was driven primarily by the rates of discontinuation due to adverse events.

• Individual results may vary.

<sup>†</sup> CD4 cells are white blood cells (also called T-cells) that help fight infections. CD4 cell count is the number of CD4<sup>+</sup> T-cells per cubic millimeter of blood.<sup>5</sup>

## IMPORTANT SAFETY INFORMATION (cont'd)

### DRUG INTERACTIONS

- Consult the full Prescribing Information for TRIUMEQ for more information on potentially significant drug interactions
- Drugs that induce or inhibit CYP3A or UGT1A1 may affect plasma concentrations of dolutegravir
- Administer TRIUMEQ 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, when taken with food, TRIUMEQ and supplements containing calcium or iron can be taken at the same time

### USE IN SPECIFIC POPULATIONS

- **Pregnancy:** There are insufficient human data on the use of TRIUMEQ 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 TRIUMEQ during the first trimester, assess the risks and benefits of continuing TRIUMEQ versus switching to another antiretroviral regimen. For individuals actively trying to become pregnant, initiation of TRIUMEQ 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 TRIUMEQ. Advise individuals of childbearing potential to consistently use effective contraception while taking TRIUMEQ

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## ADVERSE DRUG REACTIONS THROUGH WEEK 144:<sup>2,4</sup>

Grades 2 to 4 treatment-emergent adverse drug reactions (≥2% frequency)

ADVERSE REACTION	TRIUMEQ n=414	ATRIPLA n=419
<b>Psychiatric</b>		
Insomnia	3%	3%
Depression	1%	2%
Abnormal dreams	<1%	2%
<b>Nervous system</b>		
Dizziness	<1%	5%
Headache	2%	2%
<b>Gastrointestinal</b>		
Nausea	<1%	3%
Diarrhea	<1%	2%
<b>General disorders</b>		
Fatigue	2%	2%
<b>Skin and subcutaneous tissue</b>		
Rash <sup>†</sup>	<1%	6%
<b>Ear and labyrinth</b>		
Vertigo	0%	2%

<sup>†</sup>Includes pooled terms: rash, rash generalized, rash macular, rash maculopapular, rash pruritic, and drug eruption.

## IMPORTANT SAFETY INFORMATION (cont'd)

### USE IN SPECIFIC POPULATIONS (cont'd)

- **Impaired Renal Function:** TRIUMEQ is not recommended in patients with creatinine clearance <50 mL/min
- **Impaired Hepatic Function:** If a dose reduction of abacavir is required for patients with mild hepatic impairment, then the individual components of TRIUMEQ should be used

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

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### BOXED WARNING: HYPERSENSITIVITY REACTIONS AND EXACERBATIONS OF HEPATITIS B VIRUS (HBV)

#### Hypersensitivity Reactions:

- Serious and sometimes fatal hypersensitivity reactions, with multiple organ involvement, have occurred with abacavir-containing products
- Patients who carry the HLA-B\*5701 allele are at a higher risk of experiencing a hypersensitivity reaction to abacavir, although hypersensitivity reactions have occurred in patients who do not carry the HLA-B\*5701 allele

- TRIUMEQ is contraindicated in patients with a prior hypersensitivity reaction to abacavir and in HLA-B\*5701-positive patients. All patients should be screened for the HLA-B\*5701 allele prior to initiating therapy or reinitiation of therapy with TRIUMEQ unless patients have a previously documented HLA-B\*5701 allele assessment

Boxed Warning cont'd on page 8

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## Clinical information for a study of TRIUMEQ in women

### A look at the ARIA study<sup>4,6</sup>

- ▶ ARIA was a randomized, open-label,\* active-control trial in HLA-B\*5701-negative adult women with HIV-1 who had not started an HIV-1 treatment before.
- ▶ ARIA compared the efficacy and safety of 2 HIV-1 treatment regimens: TRIUMEQ once daily (n=248) vs Reyataz/Truvada/Norvir once daily (n=247) in 495 patients at 48 weeks (primary endpoint).
- ▶ At baseline, the median age of patients was 37 years, 100% were female, 55% were nonwhite, 7% had hepatitis C virus co-infection (patients with hepatitis B virus were excluded from this trial), 4% were CDC Class C (AIDS), 27% had HIV-1 RNA >100,000 copies/mL, and 51% had CD4<sup>+</sup> T-cell counts <350 cells/mm<sup>3</sup>.

\*In an open-label trial, both the patient and healthcare provider know the treatment regimen the patient is receiving.

### RESULTS AT 48 WEEKS (ABOUT A YEAR):<sup>4,6</sup>

	TRIUMEQ	Reyataz®/Truvada®/Norvir®
UNDETECTABLE VIRAL LOAD	82% of patients who took TRIUMEQ had a viral load of HIV-1 RNA <50 copies/mL	71% of patients who took Reyataz/Truvada/Norvir had a viral load of HIV-1 RNA <50 copies/mL
INCREASE IN CD4 CELL COUNTS <sup>†</sup>	234 cells/mm <sup>3</sup> was the average increase in CD4 cell count in patients who took TRIUMEQ	200 cells/mm <sup>3</sup> was the average increase in CD4 cell count in patients who took Reyataz/Truvada/Norvir
STOPPED TREATMENT DUE TO SIDE EFFECTS OR DEATH	4% of patients who took TRIUMEQ stopped taking it because of side effects	7% of patients who took Reyataz/Truvada/Norvir stopped taking them because of side effects

The difference in results was driven primarily by the lower rates of virologic failure and lower rates of discontinuation due to adverse events in women taking TRIUMEQ.

• Individual results may vary.

<sup>†</sup> CD4 cells are white blood cells (also called T-cells) that help fight infections. CD4 cell count is the number of CD4<sup>+</sup> T-cells per cubic millimeter of blood.<sup>5</sup>

### IMPORTANT SAFETY INFORMATION (cont'd)

#### BOXED WARNING: HYPERSENSITIVITY REACTIONS AND EXACERBATIONS OF HEPATITIS B VIRUS (HBV) (cont'd)

- Discontinue TRIUMEQ as soon as hypersensitivity reaction is suspected. Regardless of HLA-B\*5701 status, permanently discontinue TRIUMEQ if hypersensitivity cannot be ruled out, even when other diagnoses are possible
- Following a hypersensitivity reaction to TRIUMEQ, NEVER restart TRIUMEQ or any other abacavir-containing product

#### Exacerbations of Hepatitis B:

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

#### CONTRAINDICATIONS

- Do not use TRIUMEQ in patients who have the HLA-B\*5701 allele
- Do not use TRIUMEQ in patients with previous hypersensitivity reaction to abacavir, dolutegravir, or lamivudine
- Do not use TRIUMEQ in patients receiving dofetilide

- Do not use TRIUMEQ in patients with moderate or severe hepatic impairment

#### 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

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## ADVERSE DRUG REACTIONS THROUGH WEEK 48:<sup>4</sup>

Grades 2 to 4 treatment-emergent adverse drug reactions ( $\geq 2\%$  frequency)

ADVERSE REACTION	TRIUMEQ n=248	Reyataz®/Truvada®/Norvir® n=247
<b>Gastrointestinal</b>		
Nausea	1%	4%
Diarrhea	0%	2%
<b>Nervous System</b>		
Headache	<1%	2%
<b>Skin and Subcutaneous Tissue</b>		
Rash <sup>†</sup>	<1%	4%
<b>Hepatobiliary</b>		
Jaundice	0%	2%
Hyperbilirubinemia	0%	3%

<sup>†</sup> Includes rash, rash generalized, rash maculopapular, rash papular, and rash pruritic.

Please see additional adverse event data from the SINGLE study on page 7.

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

#### Hypersensitivity Reactions: (cont'd)

- Clinically, it is not possible to determine whether a hypersensitivity reaction with TRIUMEQ would be caused by abacavir or dolutegravir
- Discontinue TRIUMEQ immediately if signs or symptoms of 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 TRIUMEQ. 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
- Drug-induced liver injury leading to liver transplant has been reported with TRIUMEQ
- Monitoring for hepatotoxicity is recommended

#### Lactic Acidosis and Severe Hepatomegaly with Steatosis:

Fatal cases have been reported with the use of nucleoside analogues, including abacavir and lamivudine. Discontinue TRIUMEQ if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

#### Embryofetal Toxicity:

- Alternative treatments to TRIUMEQ 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 TRIUMEQ and counsel that consistent use of effective contraception is recommended while using TRIUMEQ in adolescents and adults of childbearing potential.

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

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# Helpful questions your clients can ask their healthcare providers about TRIUMEQ

- ▶ Encourage your clients to talk with their healthcare providers. Having open conversations can help find the right HIV-1 regimen for them.<sup>7</sup>
- ▶ Advise clients to remain under the care of a healthcare provider when using TRIUMEQ and to take all HIV-1 medicines exactly as prescribed.

For helpful questions your clients can take to their next appointment with a healthcare provider, tell them to visit [triumeq.com/ask](https://triumeq.com/ask), or suggest the questions below:

## IF YOUR CLIENT IS CURRENTLY ON AN HIV-1 TREATMENT:

- ▶ How do I know it's time to change my regimen?
- ▶ If my viral load is good, will taking TRIUMEQ change that?
- ▶ How is TRIUMEQ different from what I'm taking?
- ▶ What side effects can I expect?
- ▶ How will TRIUMEQ fit my lifestyle?

## IF YOUR CLIENT IS STARTING AN HIV-1 TREATMENT:

- ▶ Will taking HIV-1 medicine cure me?
- ▶ What are the benefits and risks of starting HIV-1 treatment?
- ▶ Will treatment affect my lifestyle?
- ▶ Is TRIUMEQ an option for me?
- ▶ Can I still give HIV to others, even after starting medicine?

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

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

### Myocardial Infarction (MI):

- Several observational studies have reported an association with the use of abacavir and the risk of MI; meta-analyses of randomized controlled clinical trials did not show increased risk. To date, there is no established biological mechanism to explain a potential increase in risk. In totality, the available data show inconsistency; therefore, evidence for a causal relationship between abacavir and the risk of MI is inconclusive

- The underlying risk of coronary heart disease should be considered when prescribing antiretroviral therapies, including abacavir, and action taken to minimize all modifiable risk factors (eg, hypertension, hyperlipidemia, diabetes mellitus, smoking)

### ADVERSE REACTIONS

The most common adverse reactions (incidence  $\geq 2\%$ , Grades 2-4) in treatment-naïve adults receiving TRIUMEQ were insomnia (3%), headache (2%), and fatigue (2%).

### DRUG INTERACTIONS

- Consult the full Prescribing Information for TRIUMEQ for more information on potentially significant drug interactions
- Drugs that induce or inhibit CYP3A or UGT1A1 may affect plasma concentrations of dolutegravir
- Administer TRIUMEQ 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, when taken with food, TRIUMEQ and supplements containing calcium or iron can be taken at the same time

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# Patient Savings information

Your clients may be eligible to start saving on their out-of-pocket expenses for TRIUMEQ or other ViiV Healthcare HIV medicines.

- ▶ Go to [mysupportcard.com](https://mysupportcard.com) and learn about the ViiVConnect Savings Card.
- ▶ **Subject to eligibility. Restrictions apply.**
- ▶ **The ViiVConnect Savings Card is not health insurance.**

## Could TRIUMEQ be an HIV-1 treatment to help your clients move forward?

Whether your client is about to start HIV-1 treatment, or wondering about medication options, consider talking to them about TRIUMEQ.

## IMPORTANT SAFETY INFORMATION (cont'd) USE IN SPECIFIC POPULATIONS

- **Pregnancy:** There are insufficient human data on the use of TRIUMEQ 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 TRIUMEQ during the first trimester, assess the risks and benefits of continuing TRIUMEQ versus switching to another antiretroviral regimen. For individuals actively trying to become pregnant, initiation of TRIUMEQ 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 TRIUMEQ. Advise individuals of childbearing potential to consistently use effective contraception while taking TRIUMEQ
- **Impaired Renal Function:** TRIUMEQ is not recommended in patients with creatinine clearance <50 mL/min
- **Impaired Hepatic Function:** If a dose reduction of abacavir is required for patients with mild hepatic impairment, then the individual components of TRIUMEQ should be used

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](https://www.fda.gov/medwatch), or call 1-800-FDA-1088.**

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lamivudine 300 mg tablets



**Encourage your clients to read the Important Facts about TRIUMEQ and discuss it with their healthcare providers.**

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**Leo**  
Diagnosed with  
HIV in 2003

Real patient with HIV-1 taking  
TRIUMEQ as of 2014 or later.  
Individual results may vary.  
Individual compensated for his  
time by ViiV Healthcare.

 **Triumeq**  
abacavir 600 mg/dolutegravir 50 mg/  
lamivudine 300 mg tablets



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