



Ask your healthcare provider if it could work for you, too.

# Could TRIUMEQ be an HIV-1 treatment for you to move forward with?

Whether you're considering starting HIV-1 treatment, or wondering about different medication options, talk with your healthcare team about TRIUMEQ.

TRIUMEQ is a prescription HIV-1 (Human Immunodeficiency Virus-type 1) medicine used to treat HIV-1 infection in adults and in children who weigh at least 88 pounds.



# TRIUMEQ can help you get to and maintain an undetectable viral load.

Undetectable means reducing the HIV in your blood to very low levels. Results may vary.



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

TRIUMEQ is not for use by itself in some people. Take TRIUMEQ exactly as your healthcare provider tells you.

It can be taken day or night (around the same time each day)

## You can take TRIUMEQ with or without food

### **APPROVED USES**

TRIUMEQ is a prescription HIV-1 (Human Immunodeficiency Virus-type 1) medicine used to treat HIV-1 infection in adults and in children who weigh at least 88 pounds. HIV-1 is the virus that causes AIDS. TRIUMEQ is not for use by itself in people who have or have had resistance to abacavir, dolutegravir, or lamivudine. It is not known if TRIUMEQ is safe and effective in children who weigh less than 88 pounds.

### **IMPORTANT SAFETY INFORMATION**

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

TRIUMEQ can cause serious side effects, including:

• Serious allergic reactions (hypersensitivity reaction) that can cause death have happened with TRIUMEQ and other abacavir-containing products. Your risk of this allergic reaction to abacavir is much higher if you have a gene variation called HLA-B\*5701. Your healthcare provider can determine with a blood test if you have this gene variation. If you get symptoms

from 2 or more of the following groups while taking TRIUMEQ, call your healthcare provider right away: Group 1: fever

- Group 1: rever
- Group 2: naise Group 3: nausea, vomiting, diarrhea, or stomach pain
- Group 4: generally ill feeling, extreme tiredness, or achiness
- Group 5: shortness of breath, cough, or sore throat

Your pharmacist will give you a Warning Card with a list of these symptoms. **Carry this Warning Card with you at all times.** 

Please see Important Safety Information throughout this brochure and summary on pages 14-15.

Please see Important Facts about TRIUMEQ, including Important Warnings, on pages 17-18.



### IMPORTANT SAFETY INFORMATION (cont'd)

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

If you stop taking TRIUMEQ because of an allergic reaction, never take TRIUMEQ or any other medicine that contains abacavir or dolutegravir again. If you have an allergic reaction, dispose of any unused TRIUMEQ. Ask your pharmacist how to properly dispose of medicines. If you take TRIUMEQ or any other abacavir-containing medicine again after you have had an allergic reaction, within hours you may get life-threatening symptoms that may include very low blood pressure or death. If you stop TRIUMEQ for any other reason, even for a few days, and you are not allergic to TRIUMEQ, talk with your healthcare provider before taking it again. Taking TRIUMEQ again can cause a serious allergic or life-threatening reaction, even if you never had an allergic reaction to it before. **If your healthcare provider tells you that you can take TRIUMEQ again, start taking it when you are around medical help or people who can call a healthcare provider if you need one.** 

• Worsening of hepatitis B virus in people who have HIV-1 infection. If you have HIV-1 and hepatitis B virus (HBV), your HBV may get worse (flare-up) if you stop taking TRIUMEQ. A "flare-up" is when your HBV suddenly returns in a worse way than

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

before. Worsening liver disease can be serious and may lead to death. Do not stop taking TRIUMEQ without first talking to your healthcare provider, so he or she can monitor your health.

• **Resistant hepatitis B virus.** If you have HIV-1 and hepatitis B, the hepatitis B virus can change (mutate) during your treatment with TRIUMEQ and become harder to treat (resistant).

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### The HLA-B\*5701 Screening Test

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

Ask your doctor if you have had an HLA-B\*5701 screening test. If you haven't, make sure to request one.



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



How to pronounce TRIUMEQ: TRI-u-meck.

Pill not actual size.

## IMPORTANT SAFETY INFORMATION (cont'd)

#### Who should not take TRIUMEQ?

- Do not take TRIUMEQ if you:
  - have the HLA-B\*5701 gene variation
    are allergic to abacavir, dolutegravir, lamivudine or any of the ingredients in TRIUMEQ
  - take dofetilide (Tikosyn<sup>®</sup>). Taking TRIUMEQ and dofetilide can cause serious or life-threatening side effects
  - have certain liver problems

### What are other possible side effects of TRIUMEQ?

- Serious 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 function tests during treatment with TRIUMEQ. Liver problems, including liver failure, have also happened with TRIUMEQ in people without a history of liver disease or other risk factors. Liver failure resulting in liver transplant has also been reported with TRIUMEQ. Your healthcare provider may do blood tests to check your liver function. Call your healthcare provider right away if you develop any of the signs or symptoms of liver problems listed below:
  - yellow skin, or the white part of the eyes turns yellow (jaundice)
     dark urine
  - ° dark urine
  - light-colored stools

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

• A build-up of acid in your blood (lactic acidosis), which is a serious medical emergency that can cause death. Call 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
- have unusual muscle pain
- have trouble breathing
- have stomach pain with nausea and vomiting
- feel cold, especially in your arms and legs
- feel dizzy/light-headed
- have a fast/irregular heartbeat

 You do not have the HLA-B\*5701 gene variation.

If your HLA-B\*5701 test is NEGATIVE:

- You may still have a hypersensitivity reaction to TRIUMEQ, though the risk is much lower.
- Ask your doctor if a medicine containing abacavir, like TRIUMEQ, may be right for you.

Juan Supporting Jack since 2011

### IMPORTANT SAFETY INFORMATION (cont'd)

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

- Lactic acidosis can also lead to serious liver problems, which can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). Call your healthcare provider right away if you get any of the signs or symptoms of liver problems which are listed above under "Serious liver problems." You may be more likely to get lactic acidosis or serious 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 TRIUMEQ.
- **Heart attack.** Some HIV-1 medicines, including TRIUMEQ, may increase your risk of heart attack.

### The most common side effects of TRIUMEQ include:

Jack

Diagnosed with HIV in 2010

- trouble sleeping
- tiredness
- headache

These are not all the possible side effects of TRIUMEQ. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

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

- Before you take TRIUMEQ, tell your healthcare provider about all of your medical conditions, including if you:
  - have been tested and know whether or not you have a gene variation called HLA-B\*5701

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# TRIUMEQ by the numbers

In SINGLE, a medical study with 833 adult patients who had not started an HIV-1 treatment before, **more patients got to undetectable (less than 50 copies of HIV-1 RNA in a mL of blood) with TRIUMEQ than with Atripla**<sup>®</sup>. The difference in results was mostly due to more patients stopping their medication due to side effects on Atripla than on TRIUMEQ.

Your results may vary.

### **RESULTS AT 144 WEEKS (ABOUT 3 YEARS):**

### TRIUMEQ

71% of patients who took TRIUMEQ reached undetectable.\*

### ATRIPLA

63% of patients who took Atripla reached undetectable.\*

378 cells/mm<sup>3</sup> was the average increase in CD4 cell count<sup>†</sup> in patients who took TRIUMEQ.

 $\begin{array}{l} \textbf{332} \ cells/mm^3 \\ was the average increase in CD4 \ cell \\ count^\dagger \ in \ patients \ who \ took \ Atripla. \end{array}$ 

**4%** of patients stopped taking TRIUMEQ due to side effects.

14% of patients stopped taking Atripla due to side effects.

\*Undetectable means less than 50 copies of HIV-1 RNA in a milliliter of blood. <sup>†</sup>CD4 cells are white blood cells (also called T cells) that help fight infections. CD4 cell count is the number of CD4+ T cells per cubic milliliter of blood.

# IMPORTANT SAFETY INFORMATION (cont'd)

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

- have or have had liver problems, including hepatitis B or C infection
- have kidney problems
- have heart problems, smoke, or have diseases that increase your risk of heart disease, such as high blood pressure, high cholesterol, or diabetes
- drink alcohol or take medicines that contain alcohol
  are pregnant or plan to become pregnant. One of the medicines in TRIUMEQ, called dolutegravir, may harm your unborn baby

- Your healthcare provider may prescribe a different medicine than TRIUMEQ 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 will perform a pregnancy test before you start treatment with TRIUMEQ, and you should consistently use effective birth control (contraception) during treatment with TRIUMEQ
- 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 TRIUMEO
- are breastfeeding or plan to breastfeed. Do not breastfeed if you take TRIUMEQ. Two of the medicines in TRIUMEQ (abacavir and lamivudine) pass into your breastmilk
- 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 TRIUMEQ. Keep a list of your medicines to show 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 TRIUMEQ.
- Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take TRIUMEQ with other medicines.

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### MOST COMMON MEDIUM TO SEVERE SIDE EFFECTS AT 144 WEEKS (ABOUT 3 YEARS):

TRIUMEQ

**3%** of patients experienced trouble sleeping.

**3%** of patients experienced trouble sleeping.

**ATRIPLA** 

2% of patients experienced headache.



2% of patients experienced headache.

2% of patients experienced tiredness.



2% of patients experienced tiredness.

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#### Please read the Medication Guide for TRIUMEQ and discuss it with your healthcare provider.

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 Serious allergic reactions (hypersensitivity reaction) that can cause death have happened with TRIUMEQ and other abacavir-containing products. Your risk of this allergic reaction to abacavir is much higher if you have a gene variation called HLA-B\*5701. Your healthcare provider can determine with a blood test if you have this gene variation. If you get symptoms from 2 or more of the following groups while taking TRIUMEQ, call your healthcare provider right away:

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# **Snapshots:**

Name: Peter Diagnosed with HIV in 2015 Loves: Singing Listens to: Pop, Rock & Jazz Lives for: Performing and theater Support system: My boyfriend, friends, brothers, and sisters

## IMPORTANT SAFETY INFORMATION (cont'd)

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

- Group 1: fever
- Group 2: rash
- Group 3: nausea, vomiting, diarrhea, or stomach pain
- Group 4: generally ill feeling, extreme tiredness, or achiness
- Group 5: shortness of breath, cough, or sore throat

Your pharmacist will give you a Warning Card with a list of these symptoms. **Carry this Warning Card with you at all times.** 

If you stop taking TRIUMEQ because of an allergic reaction, never take TRIUMEQ or any other medicine that contains abacavir or **dolutegravir again.** If you have an allergic reaction, dispose of any unused TRIUMEQ. Ask your pharmacist how to properly dispose of medicines. If you take TRIUMEQ or any other abacavir-containing medicine again after you have had an allergic reaction, **within** hours you may get life-threatening symptoms that may include very low blood pressure or **death**. If you stop TRIUMEQ for any other reason, even for a few days, and you are not allergic to TRIUMEQ, talk with your healthcare provider before taking it again. Taking TRIUMEQ again can cause a serious allergic or life-threatening reaction, even if you never had an allergic reaction to it before. **If your** healthcare provider tells you that you can take TRIUMEQ again, start taking it when

Please see Important Safety Information throughout this brochure and summary on pages 14-15.

Please see Important Facts about TRIUMEQ, including Important Warnings, on pages 17-18. you are around medical help or people who can call a healthcare provider if you need one.

- Worsening of hepatitis B virus in people who have HIV-1 infection. If you have HIV-1 and hepatitis B virus (HBV), your HBV may get worse (flare-up) if you stop taking TRIUMEQ. A "flare-up" is when your HBV suddenly returns in a worse way than before. Worsening liver disease can be serious and may lead to death. Do not stop taking TRIUMEQ without first talking to your healthcare provider, so he or she can monitor your health.
- **Resistant hepatitis B virus.** If you have HIV-1 and hepatitis B, the hepatitis B virus can change (mutate) during your treatment with TRIUMEQ and become harder to treat (resistant).

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

#### Name: Jeannette

Diagnosed with HIV in 2011 Loves: Going to church and writing Listens to: Contemporary Jazz Lives for: Performing on stage Support system: My brothers and childhood friends



Name: Garland Diagnosed with HIV in 2016 Loves: Dancing Listens to: R&B, Neo-Soul & Gospel Lives for: Cooking and writing music Support system: My friends

## IMPORTANT SAFETY INFORMATION (cont'd)

#### Who should not take TRIUMEQ?

#### • Do not take TRIUMEQ if you:

- have the HLA-B\*5701 gene variation
  are allergic to abacavir, dolutegravir, lamivudine or any of the ingredients in TRIUMEQ
- take dofetilide (Tikosyn<sup>®</sup>). Taking TRIUMEQ and dofetilide can cause serious or life-threatening side effects
- have certain liver problems

### What are other possible side effects of TRIUMEQ?

• Serious 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 function tests during treatment with TRIUMEQ. Liver problems, including liver failure, have also happened with TRIUMEQ in people without a history of liver disease or other risk factors. Liver failure resulting in liver transplant has also been reported with TRIUMEQ. Your healthcare provider may do blood tests to check

#### your liver function. Call your healthcare provider right away if you develop any of the signs or symptoms of liver problems listed below:

- yellow skin, or the white part of the eyes turns yellow (jaundice)
- dark urine
- light-colored stools
- loss of appetite
- nausea or vomiting
- ° pain, aching, or tenderness on the right side of your stomach area

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# Real Talk: What to say to your **Doctor**

### Before taking TRIUMEQ, tell your doctor if you:



- have been tested and know whether or not you have a gene variation called HLA-B\*5701.
- have or had liver problems, including hepatitis B or C infection; have kidney problems; have heart problems, smoke, or have diseases that increase your risk of heart disease such as high blood pressure, high cholesterol, or diabetes; drink alcohol or take medicines that contain alcohol; or have any other medical condition.
- are pregnant or plan to become pregnant. One of the medicines in TRIUMEQ, called dolutegravir, may harm your unborn baby.
- are breastfeeding or plan to breastfeed. Do not breastfeed if you take TRIUMEQ. Two of the medicines in TRIUMEQ (abacavir and lamivudine) pass into your breastmilk.

**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 TRIUMEQ. Keep a list of your medicines to show your healthcare provider and pharmacist when you get a new medicine.

## IMPORTANT SAFETY INFORMATION (cont'd)

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

- A build-up of acid in your blood (lactic acidosis), which is a serious medical emergency that can cause death. Call 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
- have unusual muscle pain
- have trouble breathing
- ° have stomach pain with nausea and vomiting
- feel cold, especially in your arms and legs
- feel dizzy/light-headed
- have a fast/irregular heartbeat

- Lactic acidosis can also lead to serious liver problems, which can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). Call your healthcare provider right away if you get any of the signs or symptoms of liver problems which are listed above under "Serious liver problems." You may be more likely to get lactic acidosis or serious 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 TRIUMEQ.

• **Heart attack.** Some HIV-1 medicines, including TRIUMEQ, may increase your risk of heart attack.

### The most common side effects of TRIUMEQ include:

- trouble sleeping
- tiredness
- headache

These are not all the possible side effects of TRIUMEQ. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

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

# Is TRIUMEQ an option you can MOVE FORWARD with?

Talk with your healthcare team to find out.

### What other medications do you take?



Some medications may affect one another and cause a bad reaction, or change the way your HIV-1 medications are supposed to work. It's important to speak openly with your HCP and tell him or her about:

- other conditions you have and the medicines you take for them
- over-the-counter medicines you take, including antacids
- vitamins, herbal medicines, sports supplements, or recreational drugs you may take

## IMPORTANT SAFETY INFORMATION (cont'd)

What should I tell my healthcare provider before taking TRIUMEQ?

- Before you take TRIUMEQ, tell your healthcare provider about all of your medical conditions, including if you:
- have been tested and know whether or not you have a gene variation called HLA-B\*5701
- have or have had liver problems, including hepatitis B or C infection
- have kidney problems
- have heart problems, smoke, or have diseases that increase your risk of heart disease, such as high blood pressure, high cholesterol, or diabetes

 drink alcohol or take medicines that contain alcohol
 are pregnant or plan to become pregnant. One of the medicines in TRIUMEQ, called dolutegravir, may harm your unborn baby

- Your healthcare provider may prescribe a different medicine than TRIUMEQ 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 will perform a pregnancy test before you start treatment with TRIUMEQ, and you should consistently use effective birth control (contraception) during treatment with TRIUMEQ
- 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 TRIUMEQ

- are breastfeeding or plan to breastfeed. Do not breastfeed if you take TRIUMEQ. Two of the medicines in TRIUMEQ (abacavir and lamivudine) pass into your breastmilk
- 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 TRIUMEQ. Keep a list of your medicines to show 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 TRIUMEQ.
- Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take TRIUMEQ with other medicines.

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Leo Diagnosed with HIV in 2003

### **IT'S YOUR LIFE.** Here's how **TRIUMEQ** fits in your day.

### When do you eat?



Whether you eat three meals a day, several smaller meals, or even if you eat just once a day, you can take TRIUMEQ with or without food. Talk to your doctor about taking TRIUMEQ:

• whatever time of day or night, as long as it's around the same time, every time

### What's your schedule?



If your doctor says TRIUMEQ is right for you, whether you're a night owl, an early bird, or have a 9-5 job, think about making it part of your:

- morning routine, like brushing your teeth
- daily activity, like going for a walk
- evening habit, like watching your favorite show

Take TRIUMEQ exactly as your healthcare provider tells you.

#### 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 Medication Guide for TRIUMEQ and discuss it with your healthcare provider.

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# Here are some things to ask at your next appointment.

### IF YOU'RE CURRENTLY ON HIV-1 TREATMENT

IF YOU'RE STARTING HIV-1 TREATMENT

- How do I know if it's time to change my HIV-1 regimen?
- If my viral load is undetectable, could taking TRIUMEQ change that?
- How is TRIUMEQ different from what I'm taking?
- What side effects can I expect?
- How will TRIUMEQ fit into my lifestyle?
- 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? What side effects can I expect?
- Can I still give HIV to others even after starting medicine?

### To download more Real Talking points, see us at TRIUMEQ.com/ask

### IMPORTANT SAFETY INFORMATION (cont'd)

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

- Group 1: fever
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take TRIUMEQ again, start taking it when you are around medical help or people who can call a healthcare provider if you need one.

• Worsening of hepatitis B virus in people who have HIV-1 infection. If you have HIV-1 and hepatitis B virus (HBV), your HBV may get worse (flare-up) if you stop taking TRIUMEQ. A "flare-up" is when your HBV suddenly returns in a worse way than before. Worsening liver disease can be serious and may lead to death. Do not stop taking TRIUMEQ without first talking to your healthcare provider, so he or she can monitor your health.

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#### Who should not take TRIUMEO?

- Do not take TRIUMEQ if you:
- have the HLA-B\*5701 gene variation ° are allergic to abacavir, dolutegravir, lamivudine or
- any of the ingredients in TRIUMEQ
- ° take dofetilide (Tikosyn®). Taking TRIUMEQ and dofetilide can cause serious or life-threatening side effects
- have certain liver problems

#### What are other possible side effects of **TRIUMEQ?**

- Serious 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 function tests during treatment with TRIUMEQ. Liver problems, including liver failure, have also happened with TRIUMEQ in people without a history of liver disease or other risk factors. Liver failure resulting in liver transplant has also been reported with TRIUMEQ. Your healthcare provider may do blood tests to check your liver function. Call your healthcare provider right away if you develop any of the signs or symptoms of liver problems listed below:
- yellow skin, or the white part of the eyes turns vellow (jaundice)
- dark urine
- light-colored stools
- loss of appetite
- nausea or vomiting
- o pain, aching, or tenderness on the right side of your stomach area
- A build-up of acid in your blood (lactic acidosis), which is a serious medical emergency that can cause death. Call your healthcare provider

#### right away if you get any of the following symptoms that could be signs of lactic acidosis:

- feel verv weak or tired
- have unusual muscle pain
- have trouble breathing
- have stomach pain with nausea and vomiting
- feel cold, especially in your arms and legs
- feel dizzy/light-headed
- have a fast/irregular heartbeat
- Lactic acidosis can also lead to serious liver problems, which can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). Call your healthcare provider right away if you get any of the signs or symptoms of liver problems which are listed above under "Serious liver problems." You may be more likely to get lactic acidosis or serious 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 TRIUMEQ.
- Heart attack. Some HIV-1 medicines, including TRIUMEQ, may increase your risk of heart attack.

#### The most common side effects of TRIUMEO include:

- trouble sleeping
- tiredness
- headache

These are not all the possible side effects of TRIUMEQ. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

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

- Before you take TRIUMEQ, tell your healthcare provider about all of your medical conditions, including if you:
- have been tested and know whether or not you have a gene variation called HLA-B\*5701
- have or have had liver problems, including hepatitis B or C infection
- have kidney problems
- have heart problems, smoke, or have diseases that increase your risk of heart disease, such as high blood pressure, high cholesterol, or diabetes

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

Please see Important Safety Information throughout this brochure and summary on pages 14-15.

Please see Important Facts about TRIUMEQ, including Important Warnings, on pages 17-18.

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

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

• drink alcohol or take medicines that contain alcohol

- ° are pregnant or plan to become pregnant. One of the medicines in TRIUMEQ, called dolutegravir, may harm your unborn baby
  - Your healthcare provider may prescribe a different medicine than TRIUMEQ 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 will perform a pregnancy test before you start treatment with TRIUMEQ, and you should consistently use effective birth control (contraception) during treatment with TRIUMEQ
  - 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 TRIUMEQ
- are breastfeeding or plan to breastfeed. Do not breastfeed if you take TRIUMEQ. Two of the medicines in TRIUMEQ (abacavir and lamivudine) pass into your breastmilk
- 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 TRIUMEQ. Keep a list of your medicines to show 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 TRIUMEQ.
- Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take TRIUMEQ 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 Medication Guide for TRIUMEQ and discuss it with your healthcare provider.

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Please see Important Safety Information throughout this brochure and summary on pages 14-15.

Please see Important Facts about TRIUMEQ, including Important Warnings, on pages 17-18. Peter Diagnosed with HIV in 2015



# You're looking ahead, so here's support that has your back.

Here are some additional resources for living with HIV.

HIV Support Resources The sites listed are external to ViiV Healthcare. ViiV Healthcare does not have control over the content of the information provided on these Web sites and, therefore, does not warrant their accuracy and completeness. US government Web sites: AIDSinfo.nih.gov CDC.gov/hiv/

Patient Savings You may be eligible to start saving on your out-of-pocket expenses for ViiV Healthcare HIV medicines.

Go to **www.mysupportcard.com** and learn about the ViiVConnect Savings Card.

Subject to eligibility. Restrictions apply.

The ViiVConnect Savings Card is not health insurance.





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### **IMPORTANT FACTS**

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

(TRI-u-meck)

### MOST IMPORTANT INFORMATION ABOUT TRIUMEQ

#### TRIUMEQ may cause serious side effects, including:

- Serious allergic reactions (hypersensitivity reaction) that can cause death have happened with TRIUMEQ and other abacavir-containing products. Your risk of this allergic reaction to abacavir is much higher if you have a gene variation called HLA-B\*5701. Your healthcare provider can determine with a blood test if you have this gene variation. If you get symptoms from 2 or more of the following groups while taking TRIUMEQ, call your healthcare provider right away: 1. fever; 2. rash; 3. nausea, vomiting, diarrhea, or stomach pain; 4. generally ill feeling, extreme tiredness, or achiness; 5. shortness of breath, cough, or sore throat. A list of these symptoms is on the Warning Card your pharmacist gives you. Carry this Warning Card with you at all times.
- If you stop taking TRIUMEQ because of an allergic reaction, never take TRIUMEQ or any medicine that contains abacavir or dolutegravir again. If you have an allergic reaction, dispose of any unused TRIUMEQ. Ask your pharmacist how to properly dispose of medicines. If you take TRIUMEQ or any other abacavir-containing medicine again after you have had an allergic reaction, within hours, you may get life-threatening symptoms that may include very low blood pressure or death. If you stop TRIUMEQ for any other reason, even for a few days, and you are not allergic to TRIUMEQ again can cause a serious allergic or life-threatening reaction, even if you never had an allergic reaction to it before. If your healthcare provider tells you that you can take TRIUMEQ again, start taking it when you are around medical help or people who can call a healthcare provider if you need one.
- Worsening of hepatitis B (HBV) infection. If you have both HIV-1 and HBV, your HBV may suddenly get worse if you stop taking TRIUMEQ. Do not stop taking TRIUMEQ without first talking to your healthcare provider, as they will need to check your health regularly for several months.
- **Resistant HBV.** If you have HIV-1 and HBV, the HBV can change (mutate) while you're on TRIUMEQ and become harder to treat (resistant).

#### **ABOUT TRIUMEQ**

 TRIUMEQ is a prescription HIV-1 medicine used to treat HIV-1 infection in adults and in children who weigh at least 88 pounds. TRIUMEQ is not for use by itself in people who have or have had resistance to abacavir, dolutegravir, or lamivudine. It is not known if TRIUMEQ is safe and effective in children who weigh less than 88 pounds.

### DO NOT TAKE TRIUMEQ IF YOU

- have a certain type of gene variation called the HLA-B\*5701 allele. Your HCP will test you for this before prescribing treatment with TRIUMEQ.
- are allergic to abacavir, dolutegravir, lamivudine or any of the ingredients in TRIUMEQ. See the full Medication Guide for a complete list of ingredients in TRIUMEQ.
- take dofetilide (Tikosyn<sup>®</sup>). Taking TRIUMEQ and dofetilide (Tikosyn) can cause serious or life-threatening side effects.
- have certain liver problems.

#### **BEFORE TAKING TRIUMEQ**

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

- have been tested and know if you have a particular gene variation called HLA-B\*5701.
- have or had any kidney or liver problems, including hepatitis B or C virus infection.
- have heart problems, smoke, or have diseases that increase your risk of heart disease, such as high blood pressure, high cholesterol, or diabetes.
- drink alcohol or take medicines that contain alcohol.
- are pregnant or plan to become pregnant. One of the medicines in TRIUMEQ, called dolutegravir, may harm your unborn baby.
  - Your healthcare provider may prescribe a different medicine than TRIUMEQ 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 will perform a pregnancy test before you start treatment with TRIUMEQ, and you should consistently use effective birth control (contraception) during treatment with TRIUMEQ.
  - 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 TRIUMEQ.
- are breastfeeding or plan to breastfeed. Do not breastfeed if you take TRIUMEQ. Two of the medicines in TRIUMEQ (abacavir and lamivudine) pass into your breastmilk.

**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 TRIUMEQ. Keep a list of your medicines to show 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 TRIUMEQ.
- Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take TRIUMEQ with other medicines.



### **IMPORTANT FACTS (cont'd)**

#### **POSSIBLE SIDE EFFECTS OF TRIUMEQ**

#### TRIUMEQ can cause serious side effects, including:

- Serious 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 function tests. Liver problems, including liver failure, have also happened with TRIUMEQ in people without a history of liver disease or other risk factors. Liver failure resulting in liver transplant has also been reported with TRIUMEQ. Your healthcare provider may do blood tests to check your liver function. Call your healthcare provider right away if you develop any of the 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), loss of appetite, nausea or vomiting, and/or pain, aching, or tenderness on the right side of your stomach area.
- A build-up of acid in your blood (lactic acidosis), which is a serious medical emergency that can cause death. Call your healthcare provider right away if you get any of the following symptoms that could be signs of lactic acidosis: feeling very weak or tired, unusual muscle pain, trouble breathing, stomach pain with nausea and vomiting, feeling cold (especially in your arms and legs), feeling dizzy or lightheaded, and/or a fast or irregular heartbeat.
- Lactic acidosis that can also lead to serious liver problems, which can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). Call your healthcare provider right away if you get any of the signs or symptoms of liver problems which are listed above under "Serious liver problems." You may be more likely to get lactic acidosis or serious 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 TRIUMEQ.
- **Heart attack.** Some HIV-1 medicines, including TRIUMEQ, may increase your risk of heart attack.

The most common side effects of TRIUMEQ are: trouble sleeping, headache, and tiredness.

These are not all the possible side effects of TRIUMEQ. Tell your healthcare provider right away if you have any new symptoms while taking TRIUMEQ. Your healthcare provider will need to do tests to monitor your health before and during treatment with TRIUMEQ.

#### **GET MORE INFORMATION**

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

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