

# HLA-B\*5701

## choosing the right

# HIV TREATMENT

### FOR YOU

Along with blood tests to measure your viral loads and CD4 cell counts, there are also blood tests to check if certain HIV medicines are right for you.

One simple test can help determine if you are at higher risk for a serious allergic reaction to an HIV medicine called **abacavir**.



### The One-Time **HLA-B\*5701** Test: Identifies people at higher risk of a serious allergic reaction

We all have unique genetic markers on our body's cells. People who have one such genetic marker—called *HLA-B\*5701*—are more likely to have an allergic reaction to abacavir.

About 8 out of 100 patients will have an allergic reaction to abacavir—one of the medicines found in EPZICOM. This simple blood test can help determine your risk.



**EPZICOM**<sup>®</sup>  
600 mg abacavir sulfate + lamivudine 300 mg  
TABLETS

## What Do Your Test Results Mean?

**Testing positive** for this genetic marker means you are at higher risk for an allergic reaction to abacavir. Treatment with abacavir is not recommended.



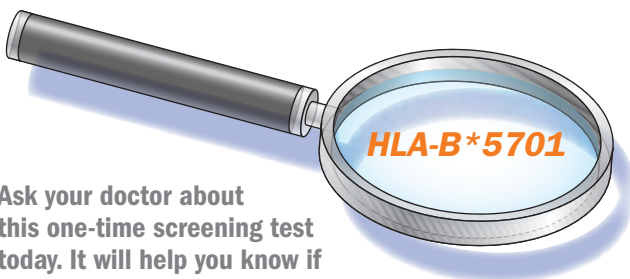
**Testing negative** for *HLA-B\*5701* means that a patient is at a lower risk of developing an allergic reaction to abacavir and therefore may be an appropriate candidate for an abacavir-containing product, like EPZICOM. However, these patients might still develop a hypersensitivity reaction and should contact their healthcare provider if they suspect such a reaction (see Important Safety Information in orange background for typical signs and symptoms).



## Who Should Get Screened?

This one-time screening test is recommended for most people with HIV as one of their routine lab tests. Those who should be tested include:

- People who have not yet started HIV treatment
- People who have started HIV treatment, but have never taken a medicine containing abacavir
  - Note: People who have been diagnosed with an abacavir hypersensitivity reaction should not receive abacavir. Therefore, the *HLA-B\*5701* test is not needed.



**Ask your doctor about this one-time screening test today. It will help you know if EPZICOM may be right for you.**

If you have questions about the information provided, ask your healthcare provider. More information, written in technical medical language for healthcare professionals, is available. You can request this information from your healthcare provider.

## What is EPZICOM?

- EPZICOM is an HIV medicine that contains 2 medicines—including abacavir
- EPZICOM was approved by the FDA\* in 2004
- EPZICOM has been well studied with different types of HIV medicines, including **NNRTIs** and **PIs**
- EPZICOM has been studied in 30 clinical trials in more than 7,400 patients of different races, sexes, and ages
- EPZICOM **helps lower viral load** and **helps raise CD4 cell count** when used as part of a complete regimen
- EPZICOM is generally well-tolerated, and most side effects do not cause people to stop taking their medicine

## Why is the Test So Important?

When making a treatment decision, it's important to have as much information as possible about your health needs.



This one-time risk screening test can help you know all about your treatment options so you can choose the right path.

**If you are unsure of your *HLA-B\*5701* status, talk to your doctor about getting tested today.**

\*FDA = Food and Drug Administration

## Important Safety Information

- EPZICOM contains abacavir, which is also contained in ZIAGEN® (abacavir sulfate) and TRIZIVIR® (abacavir sulfate, lamivudine, and zidovudine). Patients taking EPZICOM may have a **serious allergic reaction (hypersensitivity reaction) that can cause death. Your risk of this allergic reaction is much higher if you have a gene variation called *HLA-B\*5701* than if you do not. Your healthcare provider can determine with a blood test if you have this gene variation. If you get a symptom from 2 or more of the following groups while taking EPZICOM, call your doctor right away to determine if you should stop taking this medicine.**

**1: Fever**

**2: Rash**

**3: Nausea, vomiting, diarrhea, or abdominal (stomach area) pain**

**4: Generally ill feeling, extreme tiredness, or achiness**

**5: Shortness of breath, cough, or sore throat**

- Carefully read the Warning Card that your pharmacist gives you and carry it with you at all times
- **If you stop EPZICOM because of an allergic reaction, NEVER take EPZICOM or any other abacavir-containing medicine (ZIAGEN, TRIZIVIR) again.** If you take EPZICOM 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 EPZICOM for any other reason, even for a few days, and you are not allergic to EPZICOM, talk with your healthcare provider before taking it again. Taking EPZICOM again can cause a serious 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 EPZICOM again, **start taking it when you are around medical help or people who can call a healthcare provider if you need one**
- A buildup of lactic acid in the blood and an enlarged liver, including fatal cases, have been reported
- Do not take EPZICOM if your liver does not function normally
- Some patients infected with both hepatitis B virus (HBV) and HIV have worsening of hepatitis after stopping lamivudine (a component of EPZICOM). Discuss any change in treatment with your healthcare provider. If you have both HBV and HIV and stop treatment with EPZICOM, you should be closely monitored by your healthcare provider for at least several months
- Worsening of liver disease (sometimes resulting in death) has occurred in patients infected with both HIV and hepatitis C virus who are taking anti-HIV medicines and are also being treated for hepatitis C with interferon with or without ribavirin. If you are taking EPZICOM as well as interferon with or without ribavirin and you experience side effects, be sure to tell your healthcare provider
- When you start taking HIV medicines, your immune system may get stronger and could begin to fight infections that have been hidden in your body, such as pneumonia, herpes virus, or tuberculosis. If you have new symptoms after starting your HIV medicines, be sure to tell your healthcare provider

## Important Safety Information (continued)

- Changes in body fat may occur in some patients taking antiretroviral therapy. These changes may include an increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the back, chest, and stomach area. Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these conditions are not known
- Some HIV medicines, including those containing abacavir (ZIAGEN, EPZICOM, and TRIZIVIR), may increase your risk of heart attack. If you have heart problems, smoke, or suffer from diseases that increase your risk of heart disease, such as high blood pressure, high cholesterol, or diabetes, tell your healthcare provider
- The most common side effects seen with the drugs in EPZICOM dosed once daily were allergic reaction, trouble sleeping, depression, headache, tiredness, dizziness, nausea, diarrhea, rash, fever, stomach pain, abnormal dreams, and anxiety. Most of these side effects do not cause people to stop taking EPZICOM

**Get tested for *HLA-B\*5701* today to help you make informed treatment decisions.**

**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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