



# ibalizumab-uiyk (Trogarzo)

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## **WHAT IS IBALIZUMAB-UIYK?**

Ibalizumab-uiyk, also known as Hu5A8, IBA, Ibalizumab, TMB-355, or TNX-355 (brand name Trogarzo) is a drug used as part of [antiretroviral therapy \(ART\)](#). The FDA approved ibalizumab-uiyk in 2018 as an [antiretroviral drug \(ARV\)](#) for people with HIV infection. Ibalizumab-uiyk is manufactured by [Thera Technologies](#).

Ibalizumab-uiyk is a post-attachment inhibitor. Post-attachment inhibitors are a class of ARVs that bind to the CD4 receptor on a host CD4 cell. This blocks HIV from attaching to the CCR5 and CXCR4 co-receptors and entering the cell. Post-attachment inhibitors are part of a larger class of HIV drugs called [entry inhibitors](#), which include fusion inhibitors, CCR5 antagonists, attachment inhibitors, and post-attachment inhibitors. Entry inhibitors block HIV from entering host CD4 cells.

When used in combination with other ARVs to treat HIV infection, ibalizumab-uiyk may help:

- Reduce the amount of HIV in your blood. This is called [viral load](#).
- Increase the number of [CD4 cells](#) in your blood that help fight off other infections.

Reducing the amount of HIV and increasing the CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting [opportunistic infections \(OIs\)](#) that can happen when your immune system is weak. [Read more about viral suppression](#).

Ibalizumab-uiyk [does not cure](#) HIV infection or [AIDS](#). You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

## **WHO SHOULD TAKE IBALIZUMAB-UIYK?**

Ibalizumab-uiyk is a prescription HIV medicine used in combination with other ARVs to treat HIV infection in adults who:

- have received several ART regimens in the past  
**AND**
- have HIV that is resistant to many ARVs  
**AND**
- are failing their current ART regimen (this could happen because the current ART is not working or no longer works, side effects are too severe, or there are other safety reasons)

The safety and effectiveness of ibalizumab-uiyk has not been established in children under 18 years of age.

Ibalizumab-uiyk has not been carefully studied in the elderly (65 years of age and older).

All people with HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. [Read more about U.S. ART guidelines.](#)

### **WHO SHOULD NOT TAKE IBALIZUMAB-UIYK?**

Do not take ibalizumab-uiyk if you are allergic to ibalizumab-uiyk or any of the ingredients in this drug.

### **WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING IBALIZUMAB-UIYK?**

Before you take ibalizumab-uiyk tell your healthcare provider about all of your medical conditions.

Talk to your healthcare provider if you are pregnant, you plan to become pregnant, you become pregnant, or think you may be pregnant during treatment with ibalizumab-uiyk. It is not known if ibalizumab-uiyk will harm your unborn baby. There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry. [Read more about pregnancy and HIV.](#)

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with ibalizumab-uiyk. It is not known if ibalizumab-uiyk can pass to your baby in your breastmilk. You should not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your healthcare provider about the best way to feed your baby.

### **WHAT ABOUT DRUG RESISTANCE?**

Many new copies of HIV are mutations. These new copies are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called developing resistance to the drug. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. [Read more about HIV drug resistance.](#)

***Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.***

### **HOW IS IBALIZUMAB-UIYK TAKEN?**

Ibalizumab-uiyk is administered intravenously (IV) once every 14 days by a trained medical professional. The first dose of ibalizumab-uiyk is a loading dose of 2,000 mg IV followed by a maintenance dose of 800 mg IV every 2 weeks.

You will receive ibalizumab-uiyk from your healthcare provider as an infusion into your vein over 15-30 minutes. A healthcare provider will monitor you during the infusion and for a period of time after your infusion.

It is important that you receive ibalizumab-uiyk every two weeks as instructed by your healthcare provider. Do

not change the schedule of your infusions or any of your other ARVs without talking to your healthcare provider first. Tell your healthcare provider right away if you stop receiving infusions or stop taking any other ARVs.

**You need to take ibalizumab-uiyk in combination with other ARVs.** Your healthcare provider will tell you what medicines to take and how to take them.

### **WHAT ARE THE SIDE EFFECTS?**

When you start any ARV, you may have temporary [side effects](#) such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of ibalizumab-uiyk are [diarrhea](#), dizziness, nausea, and rash.

Ibalizumab-uiyk can cause serious side effects including:

**Allergic reactions.** Ibalizumab-uiyk can cause allergic reactions, including serious reactions, during and after infusion. Tell your healthcare provider or nurse, or get medical help right away if you get any of the following symptoms of an allergic reaction:

- Trouble breathing
- Swelling in your throat
- Wheezing
- Chest pain
- Chest tightness
- Cough
- Hot flush
- Nausea
- Vomiting

**Immune Reconstitution Inflammatory Syndrome (IRIS).** [IRIS](#) is a side effect that can happen when you start taking HIV medications. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. This may result in an inflammatory response which may require further evaluation and treatment. Tell your healthcare provider right away if you experience any new symptoms after starting ibalizumab-uiyk.

These are not all the possible side effects of ibalizumab-uiyk. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

### **HOW DOES IBALIZUMAB-UIYK REACT WITH OTHER DRUGS?**

All ARVs can [interact](#) with other drugs or supplements you are taking. These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take ibalizumab-uiyk with other medicines.

No drug interaction studies have been conducted with ibalizumab-uiyk. Based on ibalizumab-uiyk's mechanism of action and target-mediated drug disposition, drug-drug interactions are not expected.

***MORE INFORMATION***

Visit the [Trogarzo website](#).

Visit the [Trogarzo healthcare professional website](#).

Download the full [Prescribing Information](#).

Download the [Trogarzo Discussion Guide](#) to bring to your next medical appointment.

Apply for [Thera Patient Support](#).

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