YOUR GUIDE TO ADMINISTERING TROGARZO®
(ibalizumab-uiyk)

IV INFUSION

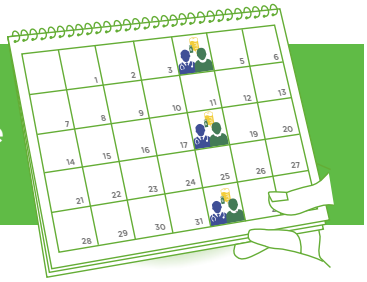
TROGARZO® must be administered by a qualified professional.

Please see IMPORTANT SAFETY INFORMATION on page 8. This can also be found in the accompanying full Prescribing Information or online at www.trogarzo.com.

Trogarzo®
(ibalizumab-uiyk)
Injection
200 mg/1.33 mL (150 mg/mL)

TROGARZO® IV INFUSION DOSING & ADMINISTRATION

TROGARZO® is administered as a single loading dose of 2,000 mg followed by a maintenance dose of 800 mg every 2 weeks as a diluted IV infusion:†



STEP 1. LOADING DOSE

2,000 mg
(10 vials)

can be administered over **30 min** as an IV infusion

60 min
observation after infusion

STEP 2. MAINTENANCE DOSE

800 mg
(4 vials)

can be administered over **15 min** as an IV infusion

15 min
observation after infusion

† TROGARZO® can also be administered as an undiluted IV push. Administration time for IV push differs from that of IV infusion. Consult the TROGARZO® Prescribing Information for complete posology.

Please see page 8 for IMPORTANT SAFETY INFORMATION.

TROGARZO® ADMINISTRATION IN 3 SIMPLE STEPS

1. Gathering supplies
2. Preparing TROGARZO®
3. Administering TROGARZO®

1. GATHERING SUPPLIES

- Latex gloves
- Alcohol swabs
- One IV infusion set
- One bag of 250 mL 0.9% Sodium Chloride Injection, USP with access port
- Saline flush 30 mL 0.9% Sodium Chloride Injection, USP

LOADING DOSE

- 2,000 mg of TROGARZO® 200 mg/1.33 mL (150 mg/mL)
  - 2,000 mg = 10 vials = 5 boxes
- Two 10-cc syringes
- Two 18-gauge needles

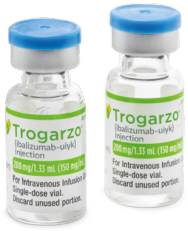
MAINTENANCE DOSE

- 800 mg of TROGARZO® 200 mg/1.33 mL (150 mg/mL)
  - 800 mg = 4 vials = 2 boxes
- One 10-cc syringe
- One 18-gauge needle

2. PREPARING TROGARZO®

A. On a clean work area, gather the appropriate dose of TROGARZO®.

- **Loading dose:**
  2,000 mg (10 vials = 13.3 mL)
- **Maintenance dose:**
  800 mg (4 vials = 5.32 mL)



Inspect the packaging and vials for integrity and ensure that no vials are expired. Verify that the solution in vials is clear and free of visible contamination. If you question the integrity of a vial or its contents, replace it with new vial.

B. Put on latex gloves and unwrap the 250 mL 0.9% Sodium Chloride Injection, USP bag.

Inspect the IV bag for integrity and ensure it is not expired. Verify that the solution in the IV bag is clear and free of visible contamination. If you question the integrity of the bag or the solution, discard and replace it with a new bag.

C. Remove the caps from the TROGARZO® vials. Wipe stoppers with alcohol swabs and discard the swabs.

D. Wipe the IV bag access port with an alcohol swab and discard the swab. If present, remove the covering from the IV bag access port before swabbing.

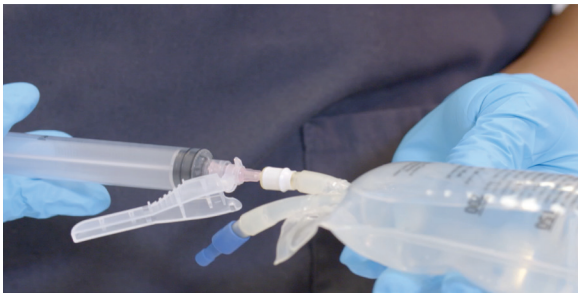
Please see page 8 for IMPORTANT SAFETY INFORMATION.

E. Uncap the 18-gauge needle and attach it to the syringe. Withdraw the appropriate dose of TROGARZO® from the vials. You will need two needles and syringes for the loading dose and one of each for the maintenance dose.

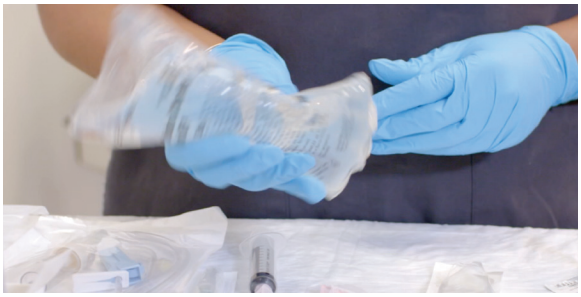
- **Loading dose**: 2,000 mg (10 vials = 13.3 mL)
- M**aintenance dose**: 800 mg (4 vials = 5.32 mL)

For a loading dose, you may have to perform two separate withdrawals and pushes into the IV bag depending on the syringe size.

F. Inject and dilute TROGARZO® into the IV bag through the access port and dispose of the needle and syringe in properly labeled sharps container.



G. Gently roll or turn the IV bag upside down to mix TROGARZO® into the solution.



H. Once mixed, TROGARZO® should be administered immediately.

If necessary, TROGARZO® can be kept at room temperature for 4 hours before being administered. TROGARZO® can also be refrigerated for up to 24 hours after being mixed, but must stand at room temperature for at least 30 minutes (but no more than 4 hours) before being administered. If not used within these timeframes, it must be discarded.

If you have questions regarding the serviceability of TROGARZO® following dilution and/or temperature excursions, please contact the Theratechnologies HUB at 1-833-238-4372.

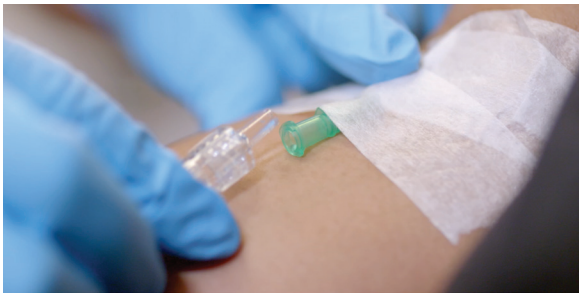
3. ADMINISTERING TROGARZO®

A. Spike the IV bag with the IV infusion set and prime the set to remove any air according to manufacturer instructions.

B. The catheter should be inserted into the cephalic vein of patient's right or left arm. If this vein is not accessible, an appropriate peripheral vein can be used.

C. Plug the IV set to the catheter and begin the infusion.

- Infuse **loading dose** over no less than **30 minutes**.
- Infuse **maintenance doses** over no less than **15 minutes** if no infusion-associated adverse reactions have previously occurred.



Please see page 8 for IMPORTANT SAFETY INFORMATION.

D. At the end of the infusion, flush the IV set with 30 mL of 0.9% Sodium Chloride Injection, USP.

E. Discard the used IV bag and infusion set in a biohazard waste container.

F. Observe the patient for infusion-associated adverse reactions:

- **60 minutes** after a loading dose of TROGARZO® for at least the first dose.
- **15 minutes** after an IV infusion maintenance dose if no infusion-associated adverse reactions were previously experienced.

IMPORTANT SAFETY INFORMATION

Indication

TROGARZO® (ibalizumab-uiyk), in combination with other antiretroviral(s), is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen.

Use in Specific Populations

- **Pregnancy:** No adequate human data are available to establish whether or not TROGARZO® poses a risk to pregnancy outcomes. Monoclonal antibodies, such as ibalizumab-uiyk, are transported across the placenta as pregnancy progresses; therefore, ibalizumab-uiyk has the potential to be transmitted from the mother to the developing fetus.
- **Lactation:** No data are available regarding the presence of TROGARZO® in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for HIV-1 transmission, instruct mothers not to breastfeed if they are receiving TROGARZO®.

Contraindications

TROGARZO® is contraindicated in patients with a prior hypersensitivity reaction to TROGARZO® or any components of the product.

Warnings and Precautions

Hypersensitivity Including Infusion-Related and Anaphylactic Reactions

- Hypersensitivity reactions including infusion-related reactions and anaphylactic reactions have been reported following infusion of TROGARZO® during post-approval use. Symptoms may include dyspnea, angioedema, wheezing, chest pain, chest tightness, cough, hot flush, nausea, and vomiting. If signs and symptoms of an anaphylactic or other clinically significant hypersensitivity reaction occur, immediately discontinue administration of TROGARZO® and initiate appropriate treatment. The use of TROGARZO® is contraindicated in patients with known hypersensitivity with TROGARZO®.

Immune Reconstitution Inflammatory Syndrome

- Immune Reconstitution Inflammatory Syndrome (IRIS) has been reported in one patient treated with TROGARZO® in combination with other antiretrovirals. During the initial phase of combination antiretroviral therapies, patients whose immune systems respond may develop an inflammatory response to indolent or residual opportunistic infections, which may necessitate further evaluation and treatment.

Embryo-Fetal Toxicity

- Based on animal data, TROGARZO® may cause reversible immunosuppression (CD4+ T cell and B cell lymphocytopenia) in infants born to mothers exposed to TROGARZO® during pregnancy. Immune phenotyping of the peripheral blood and expert consultation are recommended to provide guidance regarding monitoring and management of exposed infants based on the degree of immunosuppression observed. The safety of administering live or live-attenuated vaccines in exposed infants is unknown.

Adverse Reactions

- The most common adverse reactions (all Grades) seen in clinical trial experience, reported in at least 5% of subjects receiving TROGARZO® were diarrhea (8%), dizziness (8%), nausea (5%) and rash (5%).
- Most (90%) of the adverse reactions reported were mild or moderate in severity. Two subjects experienced severe adverse reactions: one subject had a severe rash and one subject developed IRIS manifested as an exacerbation of progressive multifocal leukoencephalopathy.

To report suspected adverse reactions, contact THERA patient support® at 1-833-23THERA (1-833-238-4372) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying full Prescribing Information or online at www.trogarzo.com.

Reference: 1. TROGARZO® Prescribing Information. Theratechnologies Inc. . December 2023.

THERA technologies

Theratechnologies Inc.
101 Hudson Street, 21st Floor,
Jersey City, New Jersey 07302
theratech.com

Trogarzo®
(ibalizumab-uiyk)
Injection
200 mg/1.33 mL (150 mg/mL)