YOUR GUIDE TO ADMINISTERING TROGARZO®
(ibalizumab-uiyk)

IV PUSH

TROGARZO® must be administered by a qualified professional.

Please see IMPORTANT SAFETY INFORMATION on page 6. 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 PUSH 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 an undiluted IV push:

LOADING DOSE
2,000 mg

can be administered over **90 seconds** via IV push

MAINTENANCE DOSE
800 mg

can be administered over **30 seconds** via IV push

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

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
- Saline flush 2-5 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

Please see page 6 for IMPORTANT SAFETY INFORMATION.

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. Allow the vials of TROGARZO® to stand at room temperature for approximately 5 minutes.

C. Put on latex gloves and remove the flip-off cap from the single-dose vial and wipe the stopper with an alcohol swab.

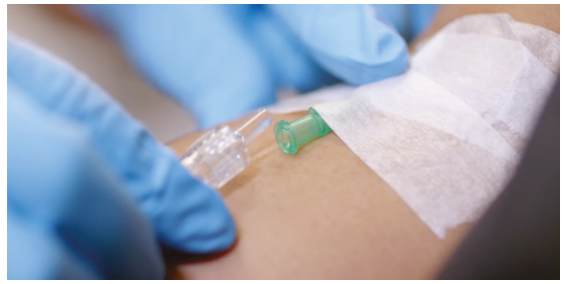
D. Uncap the 18-gauge needle and attach it to a syringe. Withdraw the appropriate dose of TROGARZO® from the vials. For the loading dose, you will have to perform two separate withdrawals.

Loading dose:
2,000 mg (10 vials = 13.3 mL)
2 needles and syringes required

Maintenance dose:
800 mg (4 vials = 5.32 mL)
1 needle and syringe required

Please see page 6 for IMPORTANT SAFETY INFORMATION.

E. **Do NOT DILUTE** the TROGARZO® solution for the IV push administration. The undiluted TROGARZO® solution should be administered immediately.



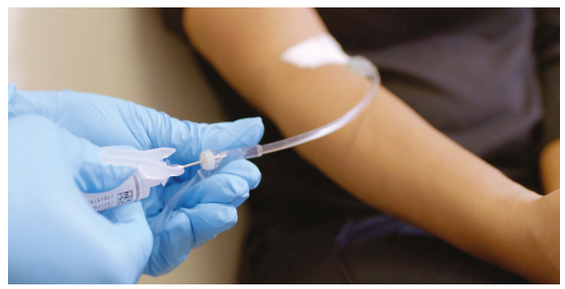
F. Discard partially used vials or empty vials of TROGARZO® and any unused portion of the undiluted TROGARZO® solution.

3. ADMINISTERING TROGARZO®

Administer TROGARZO® intravenously as an undiluted IV push over at least 90 seconds for loading dose, and over at least 30 seconds for maintenance dose.

Administer into a catheter in the cephalic vein of the patient's right or left arm. If this vein is not accessible, an appropriate peripheral vein can be used.

A. After the IV push is complete, flush with 2 to 5 mL of 0.9% Sodium Chloride Injection, USP.



B. Observe the patient for adverse reactions:

- **60 minutes** after an IV push loading dose of TROGARZO®.
- **15 minutes** after an IV push maintenance dose if no adverse reactions were previously experienced.

Additional product or infusion-related questions can be addressed by Theratechnologies Inc. Medical Affairs via your local sales representative or THERA patient support® Program in the US at 1-833-23THERA (1-833-238-4372), Monday–Friday, 8:30AM–8PM ET.

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.

Explore the simplified administration of TROGARZO® IV push for your HTE patients with HIV who are on a current ARV regimen that is failing.

SIMPLIFIED ADMINISTRATION FOR HCPS AND PATIENTS

NO DILUTION REQUIRED

LESS PREPARATION TIME COMPARED TO IV INFUSION

Scan the QR code to watch an IV push administration video

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

THERA technologies

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(ibalizumab-uiyk)
Injection
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