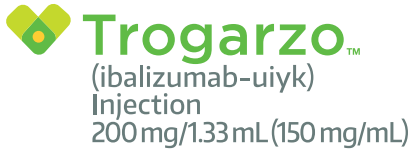
TROGARZO™
(ibalizumab-uiyk) Injection

Dosing and Administration

TROGARZO™, 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 multi-drug resistant HIV-1 infection failing their current antiretroviral regimen.



TROGARZO™ (ibalizumab-uiyk) Injection

Dosing[1]

TROGARZO™ is administered by intravenous (IV) infusion as:

- A single **loading dose** of 2,000 mg
- **Maintenance doses** of 800 mg **every 2 weeks**

If a scheduled maintenance dose is missed by 3 or more days, a loading dose should be administered as early as possible. Resume maintenance doses every 2 weeks thereafter.

- TROGARZO™ is used in combination with other antiretroviral(s).
- **Dose modifications** of TROGARZO™ are not required when administered with any other antiretrovirals or concomitant treatments.
- **Drug-drug interactions** are not expected, based on TROGARZO™'s mechanism of action and target-mediated drug disposition.

Administration[1]

Loading Dose

2,000 mg

30 min
infusion

1 hr
observation

Maintenance Doses

800 mg

15 min
infusion*

15 min
observation*

*If the patient does not experience any infusion-related adverse reactions.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- Immune Reconstitution Inflammatory Syndrome (IRIS) has been reported in 1 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.

Adverse Reactions

- The most common adverse reactions (reported in ≥5.0% of patients) 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: 1 subject had a severe rash and 1 subject developed IRIS manifested as an exacerbation of progressive multifocal leukoencephalopathy.

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™.

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

Please see the enclosed full Prescribing Information for TROGARZO™.

For more information, talk to your Theratechnologies Representative or call · THERA patient support™ at 1-833-238-4372.

Reference: 1. TROGARZO™ Prescribing Information. Theratechnologies Inc.

THERA technologies

344-01-11/17

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