LUMOXITI™ (moxetumomab pasudotox-tdfk)
for injection
Healthcare Provider Instructions for Use

Important Information

Read the following instructions before reconstitution, dilution, and administration of LUMOXITI.

- LUMOXITI must be prepared by a healthcare professional using proper aseptic technique.
- **Do not** freeze or shake LUMOXITI or IV Solution Stabilizer.
- Provide each patient the Medication Guide packaged with LUMOXITI prior to each treatment cycle to inform them of the risks and benefits of LUMOXITI.
- See Full Prescribing Information for more information on LUMOXITI.

For questions, call AstraZeneca at 1-800-236-9933.

How Supplied

- LUMOXITI and IV Solution Stabilizer are packaged separately.
- Prior to preparation, LUMOXITI and IV Solution Stabilizer should be stored at 2°C to 8°C (36°F to 46°F) in original cartons to protect from light.

LUMOXITI (moxetumomab pasudotox-tdfk)

- Each single-dose vial supplies LUMOXITI 1 mg/vial (moxetumomab pasudotox-tdfk) for injection as a lyophilized cake or powder for reconstitution and dilution prior to intravenous infusion.
  - Multiple vials of LUMOXITI may be required to administer a single dose (See Step 1: Calculate Dose).
  - **Reconstitute LUMOXITI vials with Sterile Water for Injection, USP only (not supplied).**

IV Solution Stabilizer

- Each single-dose vial contains 1 mL IV Solution Stabilizer.
- Only one vial of IV Solution Stabilizer is needed per administration of LUMOXITI, regardless of the number of vials of LUMOXITI used to prepare the infusion.
- **Do not use IV Solution Stabilizer to reconstitute LUMOXITI.**
- **Do not flush IV lines with IV Solution Stabilizer.**

Storage and Handling of Reconstituted and Diluted LUMOXITI

Table 1. Storage Times and Conditions for Reconstituted and Diluted LUMOXITI Solution

Reconstituted Solution	Diluted LUMOXITI Solution in Infusion Bag	
	After Dilution	Administration
LUMOXITI does not contain bacteriostatic preservatives. Use reconstituted solution immediately. DO NOT STORE reconstituted LUMOXITI vials.	Use diluted solution immediately or after storage at room temperature (20°C to 25°C; 68°F to 77°F) for up to 4 hours or store refrigerated at 2°C to 8°C (36°F to 46°F) for up to 24 hours. PROTECT FROM LIGHT. DO NOT FREEZE. DO NOT SHAKE.	If the diluted solution is refrigerated (2°C to 8°C; 36°F to 46°F), allow it to equilibrate at room temperature (20°C to 25°C; 68°F to 77°F) for no more than 4 hours prior to administration. Administer diluted solution within 24 hours of reconstitution as a 30-minute infusion. PROTECT FROM LIGHT.

Step 1: Calculate Dose

Calculate the dose (mg) and the number of LUMOXITI vials (1 mg/vial) to be reconstituted. The final concentration of the reconstituted LUMOXITI solution is 1 mg/mL.

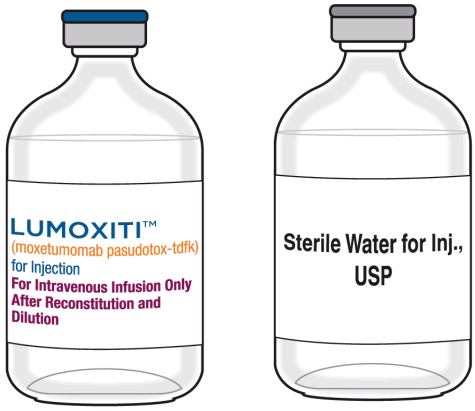
- Individualize dosing based on the patient's **actual body weight** prior to the first dose of the first treatment cycle.
  - A change in dose should only be made between cycles when a change in weight of greater than 10% is observed from the weight used to calculate the first dose of the first treatment cycle. No change in dose should be made during a particular cycle.
- **Do not** round down the dose for partial vials.

Step 2: Gather Supplies

- LUMOXITI 1 mg/vial (number of vials to be reconstituted are based on Step 1)
- 1 vial of IV Solution Stabilizer (packaged separately)
- alcohol swabs
- 1 infusion bag containing 50 mL of 0.9% Sodium Chloride Injection, USP
- Sterile Water for Injection, USP
- syringes and needles

Step 3: Reconstitution

Reconstitute each LUMOXITI vial with **1.1 mL** Sterile Water for Injection, USP using aseptic technique.



- Direct the Sterile Water for Injection, USP slowly **along the walls** of the LUMOXITI vial and not directly at the lyophilized cake or powder (see figure below).

- **Do not** reconstitute LUMOXITI vials with the IV Solution Stabilizer.
- **Gently** swirl the vial until completely dissolved. Invert the vial to ensure all cake or powder in the vial is dissolved. **Do not shake.**

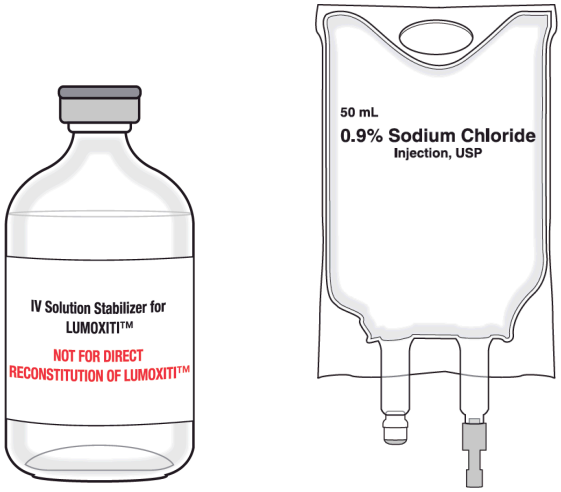
Visually inspect that the reconstituted solution is clear to slightly opalescent, colorless to slightly yellow, and free from visible particles.

- **Do not** use if solution is cloudy, discolored, or contains any particles.

The resulting 1 mg/mL solution allows a withdrawal volume of 1 mL.

Use reconstituted solution immediately. Do not store reconstituted LUMOXITI vials. See Table 1 for storage times and conditions for the reconstituted solution.

Step 4: Preparation of Infusion Bag with IV Solution Stabilizer



Obtain a 50 mL 0.9% Sodium Chloride Injection, USP infusion bag.

Only one vial of IV Solution Stabilizer is needed per administration of LUMOXITI, regardless of the number of vials of LUMOXITI used to prepare the infusion.

- Add 1 mL IV Solution Stabilizer to the infusion bag containing 50 mL 0.9% Sodium Chloride Injection, USP.
- Gently invert the bag to mix the solution. **Do not shake.**

Step 5: Dilution

Slowly withdraw the required volume of reconstituted LUMOXITI solution needed from each vial, per the calculated dose based on the patient's actual body weight (kg).

- Inject LUMOXITI into the infusion bag containing 50 mL 0.9% Sodium Chloride Injection, USP and 1 mL IV Solution Stabilizer.
- **Gently** invert the bag to mix the solution. **Do not shake.**
- Discard any partially used or empty vials of LUMOXITI and IV Solution Stabilizer.
- See Table 1 for storage times and conditions for the diluted solution.

Step 6: Intravenous Hydration and Pre-infusion Medications

Administer intravenous hydration and premedication to the patient.

- Intravenously administer 1 L of isotonic solution (e.g. 5% Dextrose Injection, USP and 0.45% or 0.9% Sodium Chloride Injection, USP) over 2 to 4 hours before each LUMOXITI infusion. Administer 0.5 L to patients under 50 kg.
- Premedicate 30 to 90 minutes prior to each LUMOXITI infusion with an antihistamine (e.g. hydroxyzine or diphenhydramine), acetaminophen, and a histamine-2 receptor antagonist (e.g. ranitidine, famotidine, or cimetidine).

Step 7: Administration

Infuse the diluted LUMOXITI solution intravenously over 30 minutes.

- **Do not** mix LUMOXITI, or administer as an infusion with other medicinal products.
- After the infusion, flush the intravenous administration line with of 0.9% Sodium Chloride Injection, USP at the same rate as the infusion. This ensures that the full LUMOXITI dose is delivered.

Step 8: Post-infusion Medications

Administer post-infusion medications.

- Intravenously administer 1 L of isotonic solution (e.g. 5% Dextrose Injection, USP and 0.45% or 0.9% Sodium Chloride Injection, USP) over 2 to 4 hours after each LUMOXITI infusion. Administer 0.5 L to patients under 50 kg.
- Consider oral antihistamines and acetaminophen for up to 24 hours following LUMOXITI infusions.
- Consider oral corticosteroid (e.g. 4 mg dexamethasone) to manage nausea and vomiting.

Maintain adequate oral fluid intake.

- Advise all patients to adequately hydrate with up to 3 L (twelve 8-oz glasses) of oral fluids (e.g. water, milk, or juice) per 24 hours on Days 1 through 8 of each 28-day treatment cycle. In patients under 50 kg, up to 2 L (eight 8-oz glasses) per 24-hour period is recommended.

Consider low-dose aspirin on Days 1 through 8 of each 28-day treatment cycle.

This Healthcare Provider Instructions for Use has been approved by the U.S. Food and Drug Administration.

Distributed by: AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850
Manufactured by: AstraZeneca AB, Södertälje, Sweden SE-151 85; U.S. License No. 2059

For more information, go to www.LUMOXITI.com or call 1-800-236-9933.
Revised: 1/2019