**ELZONRIS™ (tagraxofusp-erzs)**

**DOSE PREPARATION INSTRUCTIONS**

A step-by-step guide to facilitate ELZONRIS dose preparation prior to administration in patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN).

ELZONRIS is a preservative-free, sterile, clear, colorless, 1,000 mcg/mL solution supplied in a single-dose glass vial.

**INDICATION**

ELZONRIS is a CD123-directed cytotoxin for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and in pediatric patients 2 years and older.

**Boxed WARNING: CAPILLARY LEAK SYNDROME**

Capillary Leak Syndrome (CLS), which may be life-threatening or fatal, can occur in patients receiving ELZONRIS. Monitor for signs and symptoms of CLS and take actions as recommended.

Please see enclosed full Prescribing Information, including Boxed WARNING.

This information is intended as educational and should not replace a healthcare professional’s judgment or clinical expertise.
Key Considerations for ELZONRIS Dose Preparation

- To get started, lay out all of your components to make sure you have everything you need. Your components may vary depending on their manufacturer. However, all of the components pictured here are required for assembly of the ELZONRIS administration system.

- Please ensure all of the following components have been sourced prior to thawing ELZONRIS

- ELZONRIS is a preservative-free, sterile, clear, colorless, 1,000 mcg/mL solution supplied in a single-dose glass vial.

- ELZONRIS vials should be stored in a freezer between -25º Celsius and -15º Celsius (or between -13º Fahrenheit and 5º Fahrenheit) and protected from light by storing in the original package until time of use.

- Prior to dose preparation, thaw at room temperature—between 15º Celsius and 25º Celsius (or 59º Fahrenheit and 77º Fahrenheit)—for 15 to 30 minutes in the original carton, and verify thaw visually.

- Thawed vials may be held at room temperature for approximately 1 hour prior to dosage preparation.

- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

- Thawed ELZONRIS appearance should be a clear, colorless liquid that may contain a few white to translucent particles. Do not force thaw. Do not refreeze the vial once thawed.

- Administer ELZONRIS within 4 hours. During this 4-hour window, the prepared dose should remain at room temperature.

- Use aseptic technique for preparation of ELZONRIS dose.

Please see enclosed full Prescribing Information, including Boxed WARNING.
ELZONRIS Dose Preparation

Prepare ELZONRIS under a laminar flow hood using aseptic technique

1. Using a 10-mL syringe, withdraw 9 mL of normal saline, also known as 0.9% Sodium Chloride Injection USP, and transfer into the supplied empty 10-mL sterile vial.

2. Next, gently swirl the ELZONRIS vial to mix the contents.

3. Remove the cap and, using a sterile 1-mL syringe, withdraw 1 mL of thawed ELZONRIS from the product vial.

4. Transfer the 1 mL of ELZONRIS into the 10-mL vial containing the 9 mL of normal saline.

5. To ensure adequate mixing of the diluted ELZONRIS, gently invert the vial containing the normal saline and ELZONRIS at least 3 times. Do not shake vigorously; avoid foaming.

6. Following dilution, the final concentration of ELZONRIS is 100 mcg/mL.

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ELZONRIS Dose Preparation (cont’d)

7 As indicated earlier, the recommended dose of ELZONRIS is 12 mcg/kg diluted to 100 mcg/mL. If more than 10 mL of ELZONRIS is calculated based on the patient’s weight, ensure that the required components are available to support the dilution of a second vial and use a 20-mL sterile syringe when delivering ELZONRIS.

8 Using a new 10-mL syringe, withdraw the correct dosage volume from the vial containing the diluted ELZONRIS.

9 Cap and label the ELZONRIS-filled syringe with the ELZONRIS-provided label, and set it aside. Each label will have a unique item code number.

10 Next, take a new 10-mL syringe... and fill it with at least 3 mL of normal saline. This will be the saline flush syringe. The normal saline flush will be used to push out the full required dose of ELZONRIS to the patient at the end of the infusion.

11 Cap and label this syringe with the 0.9% Sodium Chloride Injection, USP—provided label.
ELZONRIS Dose Preparation (cont’d)

12. Attach the ELZONRIS-filled syringe to one arm of the Y-connector. Attach the saline flush syringe to the other arm of the Y-connector. Clamp off both arms until needed.

13. Connect the terminal end of the Y-connector to the microbore tubing.

14. Remove the cap from the supply side of the 0.2-micron filter and... attach it to the terminal end of the microbore tubing.

15. All components are now attached.

Please see enclosed full Prescribing Information, including Boxed WARNING.
ELZONRIS Dose Preparation (cont’d)

16. Next, prime the saline and ELZONRIS-filled lines. Unclamp the arm of the Y-connector connected to the saline flush syringe.

Prime the Y-connector up to the intersection. Do not prime the full infusion set with saline. Re-clamp the Y-connector line of the saline flush arm.

17. Remove the cap from the opposite side of the in-line filter and set it aside.

Next, unclamp the arm of the Y-connector connected to the product syringe and prime the ELZONRIS side of the Y-connector, the microbore tubing, and the in-line filter.

18. Put the cap back onto the in-line filter to ensure that ELZONRIS will not leak out.

19. The infusion set is now ready for delivery for dose administration. Finally, label the administration setup according to your institutional guidelines.

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VISIT ELZONRIS.COM/HCP FOR A DETAILED VIDEO ON HOW TO PROPERLY PREPARE ELZONRIS.
INDICATION

- ELZONRIS is a CD123-directed cytotoxin for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and in pediatric patients 2 years and older

IMPORTANT SAFETY INFORMATION

Boxed WARNING: CAPILLARY LEAK SYNDROME

- Capillary Leak Syndrome (CLS), which may be life-threatening or fatal, can occur in patients receiving ELZONRIS. Monitor for signs and symptoms of CLS and take actions as recommended

WARNINGS AND PRECAUTIONS

Capillary Leak Syndrome

- ELZONRIS can cause capillary leak syndrome (CLS), which may be life-threatening or fatal if not properly managed. The overall incidence of CLS in clinical trials was 55% in patients receiving ELZONRIS, including 46% in Grades 1 or 2, 6% in Grade 3, 1% in Grade 4, and 2 fatal events. Common signs and symptoms (incidence ≥ 20%) associated with CLS that were reported during treatment with ELZONRIS include hypoalbuminemia, edema, weight gain, and hypotension
- Before initiating therapy with ELZONRIS, ensure that the patient has adequate cardiac function and serum albumin is ≥ 3.2 g/dL
- During treatment with ELZONRIS, ensure that serum albumin levels are ≥ 3.5 g/dL and have not been reduced by ≥ 0.5 g/dL from the albumin value measured prior to dosing initiation of the current cycle. Monitor serum albumin levels prior to the initiation of each dose or more often as indicated clinically thereafter. Additionally, assess patients for other signs or symptoms of CLS, including weight gain, new onset or worsening edema including pulmonary edema, hypotension, or hemodynamic instability
- Counsel patients to seek immediate medical attention should signs or symptoms of CLS occur at any time

Hypersensitivity Reactions

- ELZONRIS can cause severe hypersensitivity reactions. Grade 3 or higher events were reported in 10% of patients in clinical trials. Monitor patients for hypersensitivity reactions during treatment with ELZONRIS. Interrupt ELZONRIS infusion and provide supportive care as needed if a hypersensitivity reaction should occur. If the reaction is severe, discontinue ELZONRIS permanently

Hepatotoxicity

- Elevations in liver enzymes can occur with ELZONRIS. Grade 3 or higher elevations in liver enzymes occurred in approximately 40% of patients in clinical trials
- Monitor alanine aminotransferase (ALT) and aspartate aminotransferase (AST) prior to each infusion with ELZONRIS. Temporarily withhold ELZONRIS if the transaminases rise to greater than 5 times the upper limit of normal (ULN) and resume treatment upon normalization or when resolved

ADVERSE REACTIONS:

The most common adverse reactions in the clinical trials (incidence ≥ 30%) are capillary leak syndrome, nausea, fatigue, peripheral edema, pyrexia, and weight increase. The most common laboratory abnormalities (incidence ≥ 50%) are decreases in albumin, platelets, hemoglobin, calcium, sodium, and increases in glucose, ALT, and AST.

Please see full Prescribing Information, including Boxed WARNING.

To report SUSPECTED ADVERSE REACTIONS, contact Stemline Therapeutics, Inc. at 1-877-332-7961 or contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.