For Pharmacists

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 injection for intravenous use 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 indicated 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 accompanying full US Prescribing Information (USPI), including Boxed WARNING, or visit ELZONRIS.com/hcp.

This information is intended as educational and should not replace a healthcare professional's judgment or clinical expertise.

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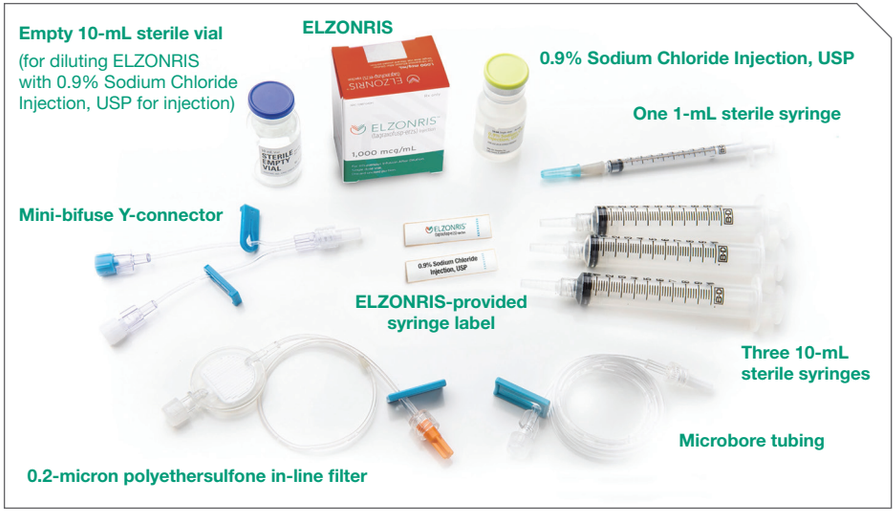
ELZONRIS®
(tagraxofusp-erzs) Injection

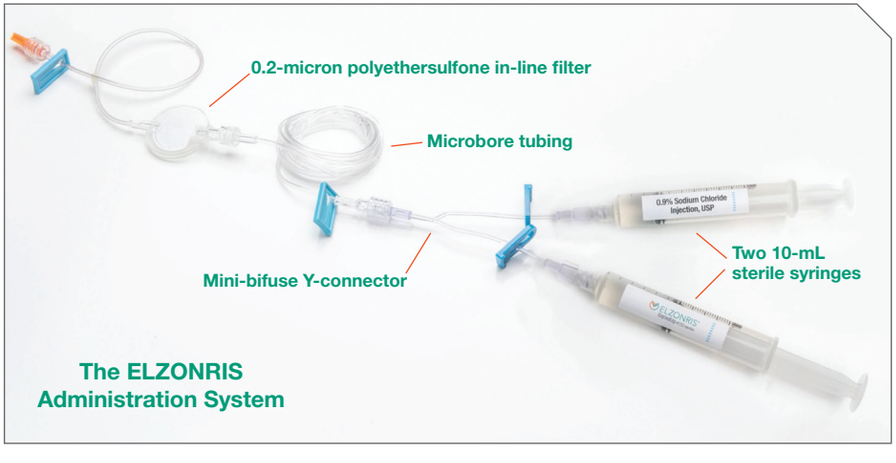
Key Considerations for ELZONRIS Dose Preparation

- 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. All components must be sterile
- Please ensure all of the following components are available prior to thawing ELZONRIS



One infusion syringe pump (not pictured).

- This is one example of an assembled administration system



- ELZONRIS injection for intravenous use 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 -25° Celsius and -15° Celsius (or between -13° Fahrenheit and 5° Fahrenheit) and protected from light
- Prior to thawing ELZONRIS, the patient's vital signs, serum albumin, transaminases, and serum creatinine levels should be checked
- Prior to dose preparation, thaw at room temperature—between 15° Celsius and 25° Celsius (or 59° Fahrenheit and 77° 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
- Administer ELZONRIS within 4 hours of completing the dose preparation. During this 4-hour window, the prepared dose should remain at room temperature
- Use aseptic technique for preparation of ELZONRIS dose
- To prepare the first dose, first calculate the required volume of diluted ELZONRIS based on the patient's body weight and then determine what components you need for preparation

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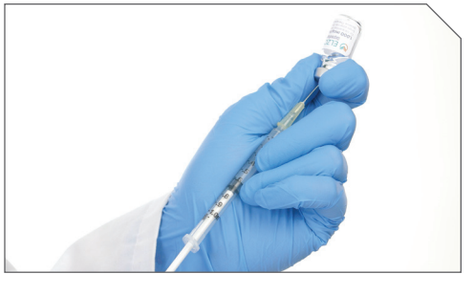
ELZONRIS Dose Preparation

Prepare ELZONRIS under a laminar flow hood using aseptic technique

1 Using a sterile 10-mL syringe, withdraw 9 mL 0.9% Sodium Chloride Injection USP, and transfer into the 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 0.9% Sodium Chloride Injection, USP.

5 To ensure adequate mixing of the diluted ELZONRIS, gently invert the vial containing the 0.9% Sodium Chloride Injection, USP 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 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 sterile syringe...

and fill it with at least 3 mL of 0.9% Sodium Chloride Injection, USP. This will be the 0.9% Sodium Chloride Injection, USP flush syringe. The 0.9% Sodium Chloride Injection, USP 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.

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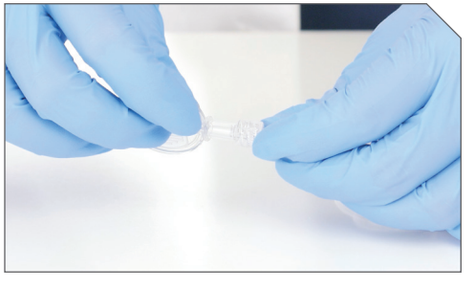
ELZONRIS Dose Preparation (cont'd)

12 Attach the ELZONRIS-filled syringe to one arm of the Y-connector.

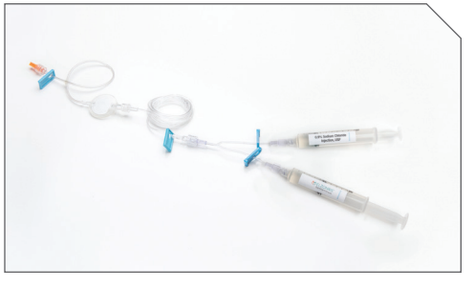
Attach the 0.9% Sodium Chloride Injection, USP syringe to the other arm of the Y-connector. Clamp off both arms until needed.

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.

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ELZONRIS Dose Preparation (cont'd)

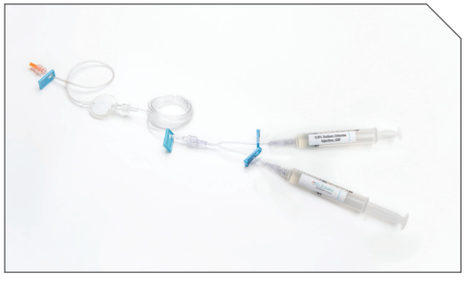
16 Next, prime the 0.9% Sodium Chloride Injection, USP and ELZONRIS-filled lines. Unclamp the arm of the Y-connector connected to the 0.9% Sodium Chloride Injection, USP flush syringe.

Prime the Y-connector up to the intersection. Do not prime the full infusion set with 0.9% Sodium Chloride Injection, USP. Re-clamp the Y-connector line of the 0.9% Sodium Chloride Injection flush arm.

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

Next, 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.

Visit ELZONRIS.com/hcp for a detailed video on how to properly prepare ELZONRIS.

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INDICATION

- ELZONRIS is a CD123-directed cytotoxin indicated 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

- Capillary leak syndrome (CLS), including life-threatening and fatal cases, has been reported among patients treated with ELZONRIS. In patients receiving ELZONRIS in clinical trials, the overall incidence of CLS was 53% (65/122), including Grade 1 or 2 in 43% (52/122) of patients, Grade 3 in 7% (8/122) of patients, Grade 4 in 1% (1/122) of patients, and four fatalities (3%). The median time to onset was 4 days (range - 1 to 46 days), and all but 5 patients experienced an event in Cycle 1.
- Before initiating therapy with ELZONRIS, ensure that the patient has adequate cardiac function and serum albumin is greater than or equal to 3.2 g/dL. During treatment with ELZONRIS, monitor serum albumin levels prior to the initiation of each dose of ELZONRIS and as indicated clinically thereafter, and assess patients for other signs or symptoms of CLS, including weight gain, new onset or worsening edema, including pulmonary edema, hypotension or hemodynamic instability.

Hypersensitivity Reactions

- ELZONRIS can cause severe hypersensitivity reactions. In patients receiving ELZONRIS in clinical trials, hypersensitivity reactions were reported in 43% (53/122) of patients treated with ELZONRIS and were Grade ≥ 3 in 7% (9/122). Manifestations of hypersensitivity reported in ≥ 5% of patients include rash, pruritus, and stomatitis. Monitor patients for hypersensitivity reactions during treatment with ELZONRIS. Interrupt ELZONRIS infusion and provide supportive care as needed if a hypersensitivity reaction should occur.

Hepatotoxicity

- Treatment with ELZONRIS was associated with elevations in liver enzymes. In patients receiving ELZONRIS in clinical trials, elevations in ALT occurred in 79% (96/122) and elevations in AST occurred in 76% (93/122). Grade 3 ALT elevations were reported in 26% (32/122) of patients. Grade 3 AST elevations were reported in 30% (36/122) and Grade 4 AST elevations were reported in 3% (4/122) of patients. Elevated liver enzymes occurred in the majority of patients in Cycle 1 and were reversible following dose interruption.
- Monitor alanine aminotransferase (ALT) and aspartate aminotransferase (AST) prior to each infusion with ELZONRIS. Withhold ELZONRIS temporarily if the transaminases rise to greater than 5 times the upper limit of normal and resume treatment upon normalization or when resolved.

ADVERSE REACTIONS:

Most common adverse reactions (incidence ≥ 30%) are capillary leak syndrome, nausea, fatigue, pyrexia, peripheral edema, and weight increase. Most common laboratory abnormalities (incidence ≥ 50%) are decreases in albumin, platelets, hemoglobin, calcium, and 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.

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