

ELZONRIS™ (tagraxofusp-erzs) DOSE ADMINISTRATION INSTRUCTIONS

A step-by-step guide to facilitate ELZONRIS dose 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

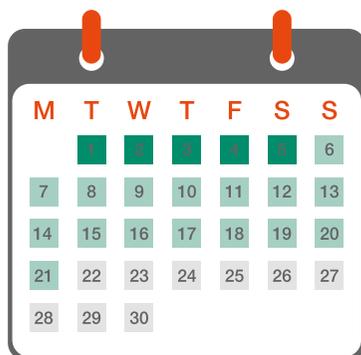
Capillary Leak Syndrome (CLS), which may be life-threatening or fatal, can occur in patients receiving ELZONRIS. Monitor for signs and symptoms of CLS and take actions as recommended.

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.

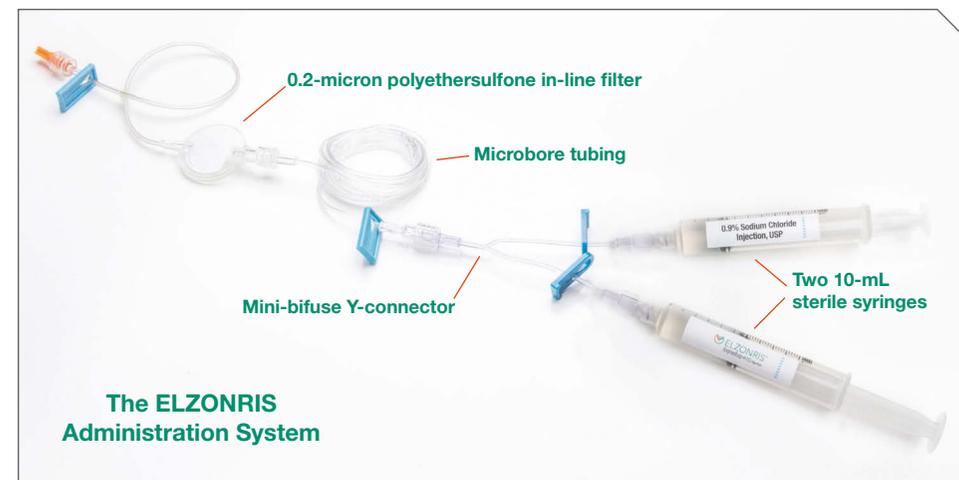
Key Considerations for ELZONRIS Dose Administration

- ▶ Prior to administration, ELZONRIS is diluted to 100 micrograms per milliliter according to the patient's weight
- ▶ ELZONRIS should be administered within 4 hours of completing the dose preparation. During this 4-hour window, the prepared ELZONRIS dose should remain at room temperature
- ▶ Do not reuse excess ELZONRIS. Any excess material should be thrown away immediately following infusion
- ▶ The recommended dose is 12 mcg/kg administered intravenously via a syringe pump over 15 minutes, including the saline flush, once daily, on days 1 through 5 of a 21-day cycle. Dosing period may be extended for dosing delays up to day 10 of the cycle



- ▶ Administer ELZONRIS until disease progression or unacceptable toxicity occurs. Do not administer as an IV push or bolus
- ▶ Prior to preparing each dose of ELZONRIS, monitor vital signs and review labs including serum albumin, transaminases, and serum creatinine levels
- ▶ Refer to the Package Insert for a complete list of Warnings and Precautions and recommended dose modifications

- ▶ Before initiating the ELZONRIS dose administration process, make sure you have everything you need. Here is an example of the ELZONRIS administration system you will receive from the pharmacy



- ▶ Some of the components you receive may look slightly different depending on the manufacturer. If the pharmacy did not include one or more of these components, such as a full syringe for the flush, you should procure your own
- ▶ Pre-medicate patients ~60 minutes prior to each infusion with
 - H1-histamine antagonist (eg, diphenhydramine hydrochloride)
 - Acetaminophen (paracetamol)
 - Corticosteroid (eg, 50 mg IV methylprednisolone or equivalent)
 - H2-histamine antagonist (eg, ranitidine)



- ▶ Administer the first cycle of ELZONRIS in the inpatient setting, with patient observation through at least 24 hours after the last infusion



- ▶ Prepare to observe patients for at least 4 hours following each infusion in subsequent cycles, which can be administered in the inpatient setting or a suitable outpatient ambulatory care setting equipped with appropriate observation for patients with hematopoietic malignancies undergoing treatment

ELZONRIS Dose Administration



1 Prior to infusion, establish venous access and maintain with sterile 0.9% Sodium Chloride Injection, USP (sterile, normal saline).



2 Insert the syringe containing the diluted ELZONRIS dose into the programmable syringe pump, following the pump's instructions. Please refer to the manufacturer's instructions for your pump to ensure proper use.



3 The total infusion time will be controlled using a programmable pump to deliver the entire diluted ELZONRIS dose over 15 minutes. This time frame includes the saline flush.



4 The pump must have settings that enable you to input the total dose amount required for infusion and the time required for delivery.



5 Before you connect the administration setup to the patient's IV line, determine where you will place the saline flush so it can be conveniently accessed upon completion of the diluted ELZONRIS dose.



6 Attach the outlet of the in-line filter to the patient's IV line.

Please see enclosed full Prescribing Information, including Boxed WARNING.

ELZONRIS Dose Administration (cont'd)



- 7** Stop the patient's running saline line by clamping it and then start the infusion pump.



Run the infusion syringe pump until the diluted ELZONRIS-filled syringe is empty. This will take less than 15 minutes.



- 8** A healthcare professional should closely observe the patient during infusion for any potential adverse or site reactions.



- 9** Depending on the type of pump you are using, alarms may sound to indicate that the syringe is almost empty. Visually verify that the syringe is completely empty.



- 10** When the diluted ELZONRIS-filled syringe is completely empty, remove it from the pump, following the pump's instructions. Do not turn off the pump.



ELZONRIS Dose Administration (cont'd)



- 11** Clamp the ELZONRIS side of the Y-connector.



- 12** Open the clamp on the saline flush side of the Y-connector.



- 13** Place the saline flush syringe in the programmable pump.



Then resume infusion via the programmable pump at the pre-specified flow rate to completely deliver the diluted ELZONRIS dose remaining in the microbore tubing line.



- 14** You should ensure that the full recommended dose of diluted ELZONRIS has been sufficiently administered during the 15-minute time frame.

ELZONRIS Dose Administration (cont'd)



- 15** When that has happened, remove the saline flush syringe from the programmable pump. The saline flush syringe will not be emptied entirely at the end of the 15-minute infusion, since it is just intended to push the remaining ELZONRIS dose out of the infusion line to complete dose delivery.



Shut down the pump by following the pump's instructions.



- 16** Disconnect the in-line filter port from the patient's IV line.

INDICATION

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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 $\geq 20\%$) 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 $\geq 30\%$) are capillary leak syndrome, nausea, fatigue, peripheral edema, pyrexia, and weight increase. The most common laboratory abnormalities (incidence $\geq 50\%$) 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.

Key Consideration for ELZONRIS Post-administration

- ▶ Prepare to observe patients through at least 24 hours after the last infusion during Cycle 1 in the inpatient setting, and observe for at least 4 hours following each infusion in subsequent cycles for any adverse events

**VISIT [ELZONRIS.COM/HCP](https://www.elzonris.com/hcp) FOR A DETAILED VIDEO
ON HOW TO ADMINISTER ELZONRIS.**

PATIENT COUNSELING INFORMATION

Capillary Leak Syndrome

Advise patients of the risk of capillary leak syndrome (CLS), and to contact their health care professional for signs and symptoms associated with CLS including new or worsening edema, weight gain, shortness of breath, and/or hypotension after infusion. Advise patients to weigh themselves daily.

Hypersensitivity

Advise patients of the risk of hypersensitivity reactions, and to contact their healthcare professional for signs and symptoms associated with hypersensitivity reactions including rash, flushing, wheezing and swelling of the face.

Hepatic Toxicity

Advise patients to report symptoms that may indicate elevated liver enzymes including fatigue, anorexia and/or right upper abdominal discomfort.

Contraception

Advise females to avoid pregnancy and to use acceptable contraceptive methods during ELZONRIS treatment and for at least 1 week after the last dose of ELZONRIS.

Lactation

Advise women not to breastfeed.



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