

# 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 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

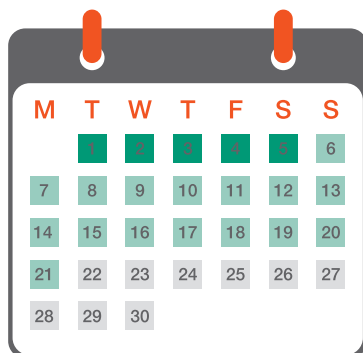
**Capillary Leak Syndrome (CLS) which may be life-threatening or fatal, can occur in patients receiving ELZONRIS. Monitor for signs and symptoms of CLS and take actions as recommended.**

Please see accompanying full US Prescribing Information (USPI), including Boxed WARNING, or visit [ELZONRIS.com/hcp](http://ELZONRIS.com/hcp).

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

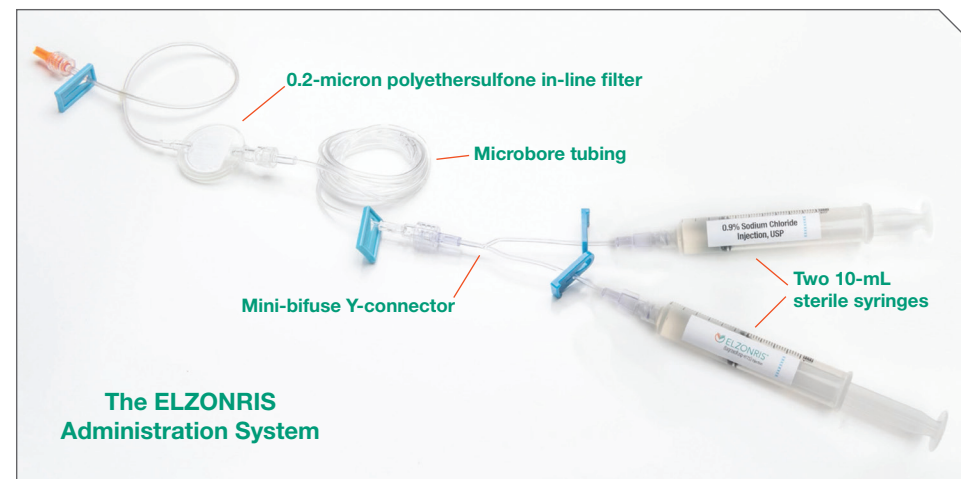
## Key Considerations for ELZONRIS Dose Administration

- ▶ 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, once daily, on days 1 through 5 of a 21-day cycle. The total infusion time will be controlled using a syringe pump to deliver the entire dose and the 0.9% Sodium Chloride Injection, USP flush over 15 minutes. Dosing period may be extended for dose 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 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, including your institution's preferred syringe pump. Here is an example of the ELZONRIS administration system you will receive from the pharmacy



- ▶ Some of the components 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, famotidine)



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



- ▶ In cycle two and beyond, prepare to observe patients for at least 4 hours following each infusion, 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

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# ELZONRIS Dose Administration



- 1 Prior to infusion, check the patient's ID band, establish venous access, and maintain with sterile 0.9% Sodium Chloride Injection, USP.



- 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 0.9% Sodium Chloride Injection, USP 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 0.9% Sodium Chloride Injection, USP 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 Y-connector of the patient's IV line.

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## ELZONRIS Dose Administration (cont'd)



- 7** Stop the patient's running 0.9% Sodium Chloride Injection, USP 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 0.9% Sodium Chloride Injection, USP flush side of the Y-connector.



- 13** Place the 0.9% Sodium Chloride Injection, USP 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.

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## ELZONRIS Dose Administration (cont'd)



- 15** When that has happened, remove the 0.9% Sodium Chloride Injection, USP flush syringe from the programmable pump. The 0.9% Sodium Chloride Injection, USP 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.



Power off the pump by following the pump's instructions.



- 16** Disconnect the in-line filter port from the patient's IV line. Prepare to monitor patient through at least 24 hours after the last infusion during Cycle 1 in the inpatient setting, and at least 4 hours following each infusion in subsequent cycles for any adverse events.

### 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  $\geq 3$  in 7% (9/122). Manifestations of hypersensitivity reported in  $\geq 5\%$  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  $\geq 30\%$ ) are capillary leak syndrome, nausea, fatigue, pyrexia, peripheral edema, and weight increase. Most common laboratory abnormalities (incidence  $\geq 50\%$ ) 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](http://www.fda.gov/medwatch).

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# Key Consideration for ELZONRIS Post-administration

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

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**Visit [ELZONRIS.com/hcp](https://www.elzonris.com/hcp) for a detailed video on how to administer ELZONRIS.**

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## 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.

### Hepatotoxicity

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 1 week after the last dose of ELZONRIS.

### Lactation

Advise women not to breastfeed.



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