

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

210660Orig1s000

LABELING

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ELCYS safely and effectively. See full prescribing information for ELCYS.

ELCYS (cysteine hydrochloride injection), for intravenous use
Initial U.S. Approval: 1971

INDICATIONS AND USAGE

ELCYS is a sulfur-containing amino acid indicated to meet the nutritional requirements of newborn infants requiring total parenteral nutrition (TPN); and of adult and pediatric patients with severe liver disease who may have impaired enzymatic processes and require TPN. It can also be added to amino acid solutions to provide a more complete profile of amino acids for protein synthesis. (1)

DOSAGE AND ADMINISTRATION

- ELCYS is for *admixing use only*. *Not for direct intravenous infusion*. (2.1)
- See full prescribing information for information on preparation, administration, instructions for use, dosing considerations, including the recommended dosage in pediatric patients and adults. (2.1, 2.2, 2.3, 2.4, 2.5)

DOSAGE FORMS AND STRENGTHS

Injection: 500 mg/10 mL (50 mg/mL) cysteine hydrochloride, USP in a 10 mL single-dose vial. (3)

CONTRAINDICATIONS

- Hypersensitivity to one or more amino acids (4)
- Inborn errors of amino acid metabolism (4)
- Pulmonary edema or acidosis due to low cardiac output (4)

WARNINGS AND PRECAUTIONS

- **Pulmonary Embolism due to Pulmonary Vascular Precipitates:** If signs of pulmonary distress occur, stop the infusion and initiate a medical evaluation. (5.1)

- **Vein Damage and Thrombosis:** Solutions with osmolarity of 900 mOsm/L or more must be infused through a central catheter. (2.1, 5.2)
- **Increased blood urea nitrogen (BUN):** Monitor laboratory parameters and discontinue if exceeds normal postprandial limits and continues to increase. (5.3)
- **Acid-Base Imbalance:** Monitor laboratory parameters and supplement with electrolytes as needed. (5.4)
- **Hepatobiliary Disorders:** Monitor liver function parameters and ammonia levels. (5.5)
- **Hyperammonemia:** Neurocognitive delay possible in infants; monitor blood ammonia levels. (5.6, 8.4)
- **Aluminum Toxicity:** Increased risk in patients with renal impairment, including preterm infants. (5.7, 8.4)
- **Monitoring and Laboratory Tests:** Monitor fluid and electrolytes, serum osmolarity, blood glucose, kidney and liver function, blood count and coagulation parameters throughout treatment. (5.8)

ADVERSE REACTIONS

Most common adverse reactions are local reactions (warm sensation, erythema, phlebitis and thrombosis at the infusion site), generalized flushing, fever and nausea (6).

To report SUSPECTED ADVERSE REACTIONS, contact Exela Pharma Sciences, LLC at 1-888-451-4321 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 04/2019

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

ELCYS is indicated for use as an additive to amino acid solutions to meet the nutritional requirements of newborn infants requiring total parenteral nutrition (TPN) and of adult and pediatric patients with severe liver disease who may have impaired enzymatic processes and require TPN. It can also be added to amino acid solutions to provide a more complete profile of amino acids for protein synthesis.

2 DOSAGE AND ADMINISTRATION

2.1 Important Administration Information

ELCYS is for *admixing use* only. It is *not for direct intravenous infusion*. Prior to administration, ELCYS *must be diluted and used as an admixture* in parenteral nutrition (PN) solutions.

The resulting solution is for intravenous infusion into a central or peripheral vein. The choice of a central or peripheral venous route should depend on the osmolarity of the final infusate. Solutions with osmolarity of 900 mOsm/L or greater must be infused through a central catheter [*see Warnings and Precautions (5.2)*].

2.2 Preparation and Administration Instructions

- ELCYS is *not for direct intravenous infusion*. Prior to administration, ELCYS *must be diluted and used as an admixture* in PN solutions.
- ELCYS is to be prepared only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area). The key factor in the preparation is careful aseptic technique to avoid inadvertent touch contamination during mixing of solutions and addition of other nutrients.
- ELCYS is for addition to amino acid solutions prior to further admixing with dextrose injection using a PN container.
- Use a dedicated line for PN solutions.
- Intravenous lipid emulsions can be infused concurrently into the same vein as ELCYS containing amino acid and dextrose solutions by a Y-connector located near the infusion site; flow rates of each solution should be controlled separately by infusion pumps.
- For administration without lipid emulsion, use a 0.22 micron in-line filter.
- To prevent air embolism, use a non-vented infusion set or close the vent on a vented set, avoid multiple connections, do not connect flexible containers in series, fully evacuate residual gas in the container prior to administration, do not pressurize the flexible container to increase flow rates, and if administration is controlled by a pumping device, turn off pump before the container runs dry.
- If infused with lipid emulsion, do not use administration sets and lines that contain di-2-ethylhexyl phthalate (DEHP). Administration sets that contain polyvinyl chloride (PVC) components have DEHP as a plasticizer.
- Visually inspect the diluted PN solution containing ELCYS for particulate matter before admixing, after admixing, and prior to administration. The solution should be clear and there should be no precipitates. A slight yellow color does not alter the quality and efficacy of this product.

2.3 Preparation Instructions for Admixing Using a Parenteral Nutrition (PN) Container

- Remove ELCYS vial from the carton and inspect for particulate matter.
- Transfer the required amount of ELCYS to an amino acid solution using strict aseptic techniques to avoid microbial contamination.
- The amino acid solution containing ELCYS can then be used to prepare admixtures in the PN container using strict aseptic techniques.
- Amino acids solution containing ELCYS may be mixed with dextrose injection. The following proper mixing sequence must be followed to minimize pH related problems:
 1. Transfer dextrose injection to the parental nutrition pooling container
 2. Transfer phosphate salt
 3. Transfer ELCYS-containing amino acid solution
 4. Transfer electrolytes
 5. Transfer trace elements
- Use gentle agitation during admixing to minimize localized concentration effects; shake containers gently after each addition.
- For automated compounding, refer to Instructions for Use of the applicable compounder.
- Because additives may be incompatible, evaluate all additions to the PN container for compatibility and stability of the resulting preparation. Consult with pharmacist, if available. Questions about compatibility may be directed to Exela Pharma Sciences, LLC. If it is deemed advisable to introduce additives to the PN container, use aseptic technique.
- Inspect the final PN solution containing ELCYS to ensure that precipitates have not formed during mixing or addition on additives. Discard if any precipitates are observed.

Stability and Storage

- For single use only. Discard used container of ELCYS.
- Use of ELCYS for admixing should be limited to up to 4 hours at room temperature (25°C/77°F) after the container closure has been penetrated. Discard any remaining drug.
- Use PN solution containing ELCYS promptly after mixing. Any storage of the admixture should be under refrigeration and limited to a brief period of time, no longer than 24 hours. After removal from refrigeration, use promptly and complete the infusion within 24 hours. Discard any remaining admixture.
- Protect PN solution from light.

2.4 Dosing Considerations

- The dosage of the final PN solution containing ELCYS must be based on the concentrations of all components in the solution and the recommended nutritional requirements [see *Dosage and Administration (2.5)*]. Consult the prescribing information of all added components to determine the recommended nutritional requirements for dextrose and lipid emulsion, as applicable.

- The dosage of ELCYS should be individualized based on the patient’s clinical condition (ability to adequately metabolize amino acids), body weight and nutritional/fluid requirements, as well as additional energy given orally/enterally to the patient. Prior to initiating parenteral nutrition, the following patient information should be reviewed: review of all medications, gastrointestinal function and laboratory data (such as electrolytes (including magnesium, calcium, and phosphorus), glucose, urea/creatinine, liver panel, complete blood count and triglyceride level (if adding lipid emulsion)).
- Prior to administration of PN solution containing ELCYS, correct severe fluid, electrolyte and acid-base disorders.

2.5 Recommended Dosage in Pediatric Patients and Adults

The recommended dosage and volume of ELCYS is shown in Table 1 and is based upon the recommended daily protein (amino acids) requirement. For pediatric patients from birth to less than 12 years of age, the recommended dosage of ELCYS is 22 mg/gram of amino acids. For adults and pediatric patients 12 years of age and older, the recommended dosage of ELCYS is 7 mg/gram of amino acids.

Table 1. Recommended Daily Dosage of ELCYS in Pediatric Patients and Adults

Age	Recommended Protein ^a Requirement (g AA/kg/day) ¹	Recommended Dosage (mg ELCYS/g AA)	Recommended Volume (mL ELCYS/g AA)
Preterm and term infants less than 1 month of age	3 to 4	22	0.44
Pediatric patients 1 month to less than 1 year of age	2 to 3	22	0.44
Pediatric patients 1 year to 11 years of age	1 to 2	22	0.44
Pediatric patients 12 years to 17 years of age	0.8 to 1.5	7	0.14
Adults: Stable Patients	0.8 to 1	7	0.14
Adults: Critically Ill Patients ^b	1.5 to 2	7	0.14

AA = Amino Acid

^aProtein is provided as amino acids (AA).

^bIncludes patients requiring more than 2 to 3 days in the intensive care unit with organ failure, sepsis or postoperative major surgery. Do not use in patients with conditions that are contraindicated [see *Contraindications (4)*]

ELCYS contains 50 mg/mL of cysteine hydrochloride (equivalent to 34.5 mg/mL of cysteine). Therefore, the ELCYS dosages in Table 1 provide:

- 15 mg cysteine/gram of amino acids for pediatric patients less than 12 years of age
- 5 mg cysteine/gram of amino acids for adults and pediatric patients 12 years of age and older

3 DOSAGE FORMS AND STRENGTHS

Injection: 500 mg/10 mL (50 mg/mL) cysteine hydrochloride, USP as a clear, colorless, sterile solution in a 10 mL single-dose vial.

4 CONTRAINDICATIONS

ELCYS is contraindicated in:

- Patients with known hypersensitivity to one or more amino acids.
- Patients with inborn errors of amino acid metabolism due to risk of severe metabolic or neurologic complications.
- Patients with pulmonary edema or acidosis due to low cardiac output.

5 WARNINGS AND PRECAUTIONS

5.1 Pulmonary Embolism due to Pulmonary Vascular Precipitates

Pulmonary vascular precipitates causing pulmonary vascular emboli and pulmonary distress have been reported in patients receiving PN. In some fatal cases, pulmonary embolism occurred as a result of calcium phosphate precipitates. Precipitation following passage through an in-line filter and suspected in vivo precipitate formation has also been reported. If signs of pulmonary distress occur, stop the PN infusion and initiate a medical evaluation. In addition to inspection of the solution [*see Dosage and Administration (2.1, 2.2)*], the infusion set and catheter should also periodically be checked for precipitates.

5.2 Vein Damage and Thrombosis

ELCYS must be diluted and used as an admixture in PN solutions. It is not for direct intravenous infusion. Solutions with an osmolarity of 900 mOsm/L or greater must be infused through a central catheter [*see Dosage and Administration (2.1)*]. The infusion of hypertonic nutrient injections into a peripheral vein may result in vein irritation, vein damage, and/or thrombosis. The primary complication of peripheral access is venous thrombophlebitis, which manifests as pain, erythema, tenderness or a palpable cord. Remove the catheter as soon as possible, if thrombophlebitis develops.

5.3 Increased Blood Urea Nitrogen (BUN)

Intravenous infusion of amino acids may induce a rise in blood urea nitrogen (BUN), especially in patients with impaired hepatic or renal function. Appropriate laboratory tests should be performed periodically and infusion discontinued if BUN levels exceed normal postprandial limits and continue to rise. It should be noted that a modest rise in BUN normally occurs as a result of increased protein intake.

Administration of amino acid solutions in the presence of impaired renal function may augment an increasing BUN, as does any protein dietary component.

5.4 Acid-Base Imbalance

Administration of ELCYS may result in metabolic acidosis in preterm infants.

Administration of amino acid solutions to a patient with hepatic impairment may result in serum amino acid imbalances, metabolic alkalosis, prerenal azotemia, hyperammonemia, stupor and coma.

Frequent clinical evaluation and laboratory determinations are necessary for proper monitoring of acid-base balance during parenteral nutrition therapy. Significant deviations from normal concentrations may require the use of additional electrolyte supplements.

5.5 Hepatobiliary Disorders

Hepatobiliary disorders are known to develop in some patients without preexisting liver disease who receive PN, including cholecystitis, cholelithiasis, cholestasis, hepatic steatosis, fibrosis and cirrhosis, possibly leading to hepatic failure. The etiology of these disorders is thought to be multifactorial and may differ between patients.

Monitor liver function parameters and ammonia levels. Patients developing signs of hepatobiliary disorders should be assessed early by a clinician knowledgeable in liver diseases in order to identify possible causative and contributory factors, and possible therapeutic and prophylactic interventions.

5.6 Hyperammonemia

Hyperammonemia is of special significance in infants, as it can result in neurocognitive delays. Therefore, it is essential that blood ammonia levels be measured frequently in infants.

Instances of asymptomatic hyperammonemia have been reported in patients without overt liver dysfunction. The mechanisms of this reaction are not clearly defined but may involve genetic defects and immature or subclinically impaired liver function [see *Contraindications (4)*, *Use in Specific Populations (8.4)*].

5.7 Aluminum Toxicity

ELCYS contains aluminum that may be toxic.

Aluminum may reach toxic levels with prolonged parenteral administration in patients with renal impairment. Preterm infants are particularly at risk for aluminum toxicity because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which also contain aluminum.

Patients with renal impairment, including preterm infants, who receive greater than 4 to 5 mcg/kg/day of parenteral aluminum can accumulate aluminum to levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

Exposure to aluminum from ELCYS is not more than 0.21 mcg/kg/day when preterm and term infants less than 1 month of age are administered the recommended maximum dosage of ELCYS (15 mg cysteine/g of amino acids and 4 g of amino acids/kg/day) [see *Table 1, Dosage and Administration (2.5)*]. When prescribing ELCYS for use in PN containing other small volume parenteral products, the total daily patient exposure to aluminum from the admixture should be considered and maintained at no more than 5 mcg/kg/day [see *Use in Specific Populations (8.4)*].

5.8 Monitoring and Laboratory Tests

Monitor fluid and electrolyte status, serum osmolarity, blood glucose, liver and kidney function, blood count and coagulation parameters throughout treatment [see *Dosage and Administration (2.4)*].

6 ADVERSE REACTIONS

The following serious adverse reactions are discussed in greater detail in other sections of the prescribing information:

- Pulmonary embolism due to pulmonary vascular precipitates [see *Warnings and Precautions (5.1)*]
- Vein damage and thrombosis [see *Warnings and Precautions (5.2)*]
- Increased BUN [see *Warnings and Precautions (5.3)*]
- Acid-base imbalance [see *Warnings and Precautions (5.4)*]
- Hepatobiliary disorders [see *Warnings and Precautions (5.5)*]
- Hyperammonemia [see *Warnings and Precautions (5.6)*]
- Aluminum toxicity [see *Warnings and Precautions (5.7)*]

Adverse reactions with the use of cysteine hydrochloride injection were identified in clinical studies or postmarketing reports. Because some of these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- Local infusion site reactions, including a warm sensation, erythema, phlebitis and thrombosis at the infusion site
- Generalized flushing, fever and nausea

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Appropriate administration of ELCYS is not expected to cause major birth defects, miscarriage or adverse maternal or fetal outcomes. Animal reproduction studies have not been conducted with cysteine hydrochloride.

The estimated background risk for major birth defects and miscarriage for the indicated populations is unknown. All pregnancies have a background risk of birth defect, loss or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defect and miscarriage in the clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

8.2 Lactation

Risk Summary

Data available on the effects of cysteine hydrochloride on infants, either directly or through breastmilk, do not suggest a significant risk of adverse events from exposure. Although there are no data on the presence of cysteine hydrochloride in human or animal milk or the effects on milk production, appropriate administration of ELCYS is not expected to cause harm to a breastfed infant. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for ELCYS and any potential adverse effects on the breastfed infant from ELCYS or from the underlying maternal condition.

8.4 Pediatric Use

ELCYS is approved for use in pediatric patients, from birth to 17 years of age, for use as an additive to amino acid solutions to meet the nutritional requirements of newborn infants, including preterm infants, requiring total parenteral nutrition (TPN) and pediatric patients with severe liver disease who may have impaired enzymatic processes and require TPN. The safety profile for ELCYS use in pediatric patients includes risks of acid-base imbalance and hyperammonemia.

Acid-base imbalance, including metabolic acidosis, may occur with ELCYS administration in preterm infants. Frequent clinical and laboratory assessments are necessary to monitor and manage fluid balance, electrolyte concentrations, and acid-base balance during parenteral nutrition therapy [*see Warnings and Precautions (5.4)*].

Hyperammonemia is of special significance in infants (birth to two years of age). This reaction appears to be related to a deficiency of the urea cycle amino acids of genetic or product origin. It is essential that blood ammonia be measured frequently in infants [*see Warnings and Precautions (5.6)*].

Because of immature renal function, preterm infants receiving prolonged PN treatment with ELCYS may be at higher risk of aluminum toxicity [*see Warnings and Precautions (5.7)*].

8.5 Geriatric Use

Clinical studies with ELCYS have not been performed to determine whether patients aged 65 and over respond differently from younger patients.

8.6 Renal Impairment

Monitor patients with impaired renal function receiving PN solutions containing the recommended dosage of ELCYS with frequent clinical evaluation and laboratory tests to assess renal function, including serum electrolytes and fluid balance [*see Dosage and Administration (2.4), Warnings and Precautions (5.8)*].

8.7 Hepatic Impairment

Monitor patients with impaired liver function receiving PN solutions containing the recommended dosage of ELCYS with frequent clinical evaluation and laboratory tests to assess liver function, such as bilirubin and liver function parameters [*see Dosage and Administration (2.4), Warnings and Precautions (5.8)*].

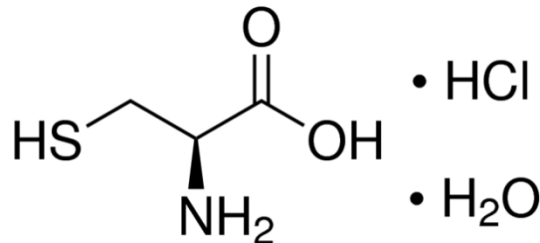
10 OVERDOSAGE

In the event of over hydration or solute overload, re-evaluate the patient and institute appropriate corrective measures [*see Warnings and Precautions (5.3, 5.4, 5.5, 5.7, 5.8)*].

11 DESCRIPTION

ELCYS (cysteine hydrochloride injection) is a sterile, nonpyrogenic solution for intravenous use. Each 10 mL of ELCYS contains 500 mg of cysteine hydrochloride, USP (equivalent to 345 mg of cysteine) in water for injection. Sodium hydroxide and/or hydrochloric acid are used as needed to adjust the pH. The pH range is 1.0 to 2.5.

The active ingredient is cysteine hydrochloride. Cysteine is a sulfur-containing amino acid. The chemical name of cysteine hydrochloride is L-cysteine hydrochloride monohydrate and is chemically designated as $C_3H_7NO_2S \cdot HCl \cdot H_2O$ having a molecular weight of 175.63. Cysteine hydrochloride is a white crystalline powder soluble in water. Cysteine aqueous solution is prone to oxidation when exposed to air, and when mixed with amino acids solutions, cysteine may convert to insoluble cystine which leads to precipitation over time. It has the following structural formula:



ELCYS contains no more than 120 mcg/L of aluminum.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Endogenous cysteine is synthesized from methionine by the enzyme, cystathionase, via the trans-sulfuration pathway, and serves as a precursor substrate for both glutathione and taurine. ELCYS provides cysteine to the systemic circulation of patients who require PN and cannot synthesize adequate quantities of cysteine due to insufficient or deficient cystathionase activity.

15 REFERENCES

1. Ayers P. et al. A.S.P.E.N. Parenteral Nutrition Handbook, 2nd ed. 2014 pg. 123 and 124.

16 HOW SUPPLIED/STORAGE AND HANDLING

ELCYS is supplied as follows:

500 mg/10 mL (50 mg/mL) of cysteine hydrochloride, USP is a clear, colorless, sterile and nonpyrogenic solution in 10 mL single-dose vials (51754-1007-1), packaged as 10 per carton (NDC 51754-1007-3)

Store at 20°C to 25°C (68°F to 77°F). [See USP Controlled Room Temperature]. Avoid excessive heat. Protect from freezing. If accidentally frozen, discard the vial.

For storage of admixed solution see *Dosage and Administration* (2.3).

17 PATIENT COUNSELING INFORMATION

Inform patients, caregivers, or home healthcare providers of the following risks of ELCYS:

- Pulmonary embolism due to pulmonary vascular precipitates [see *Warnings and Precautions* (5.1)]

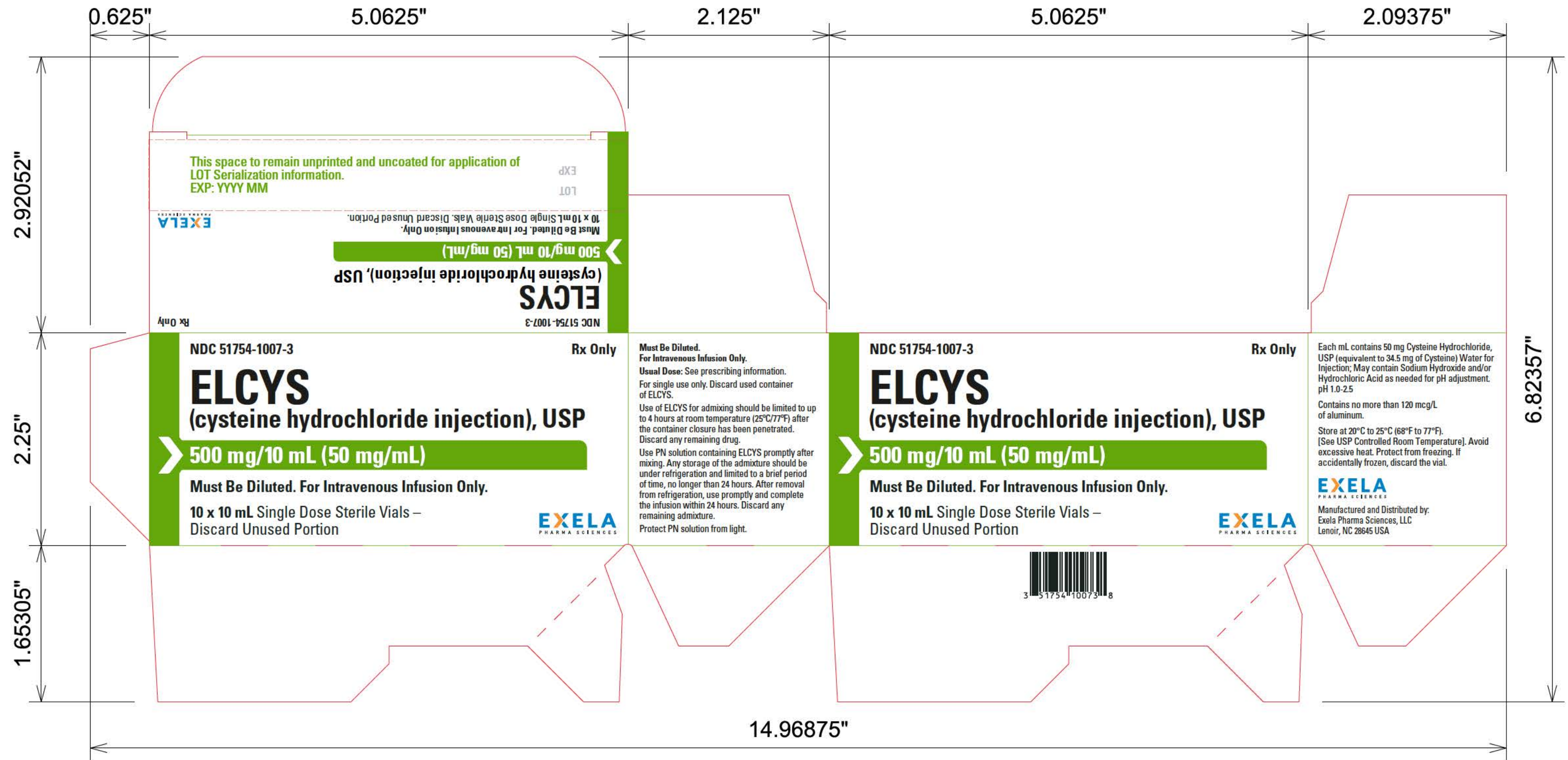
- Vein damage and thrombosis [*see Warnings and Precautions (5.2)*]
- Increased BUN [*see Warnings and Precautions (5.3)*]
- Acid base imbalance [*see Warnings and Precautions (5.4)*]
- Hepatobiliary disorders [*see Warnings and Precautions (5.5)*]
- Hyperammonemia [*see Warnings and Precautions (5.6)*]
- Aluminum toxicity [*see Warnings and Precautions (5.7)*]
- Monitoring and laboratory tests [*see Warnings and Precautions (5.8)*]

Manufactured and Distributed by:



Exela Pharma Sciences, LLC
Lenoir, NC 28645

EXELA PHARMA SCIENCES, LLC
CC11588A
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LOT Serialization information.
EXP: YYYY MM

EXP
LOT



Must Be Diluted. For Intravenous Infusion Only.
10 x 10 mL Single Dose Sterile Vials. Discard Unused Portion.

500 mg/10 mL (50 mg/mL)

ELCYS
(cysteine hydrochloride injection), USP

Rx Only

NDC 51754-1007-3

NDC 51754-1007-3

Rx Only

ELCYS
(cysteine hydrochloride injection), USP

500 mg/10 mL (50 mg/mL)

Must Be Diluted. For Intravenous Infusion Only.

10 x 10 mL Single Dose Sterile Vials –
Discard Unused Portion



Must Be Diluted.
For Intravenous Infusion Only.
Usual Dose: See prescribing information.
For single use only. Discard used container
of ELCYS.
Use of ELCYS for admixing should be limited to up
to 4 hours at room temperature (25°C/77°F) after
the container closure has been penetrated.
Discard any remaining drug.
Use PN solution containing ELCYS promptly after
mixing. Any storage of the admixture should be
under refrigeration and limited to a brief period
of time, no longer than 24 hours. After removal
from refrigeration, use promptly and complete
the infusion within 24 hours. Discard any
remaining admixture.
Protect PN solution from light.

NDC 51754-1007-3

Rx Only

ELCYS
(cysteine hydrochloride injection), USP

500 mg/10 mL (50 mg/mL)

Must Be Diluted. For Intravenous Infusion Only.

10 x 10 mL Single Dose Sterile Vials –
Discard Unused Portion



Each mL contains 50 mg Cysteine Hydrochloride,
USP (equivalent to 34.5 mg of Cysteine) Water for
Injection; May contain Sodium Hydroxide and/or
Hydrochloric Acid as needed for pH adjustment.
pH 1.0-2.5
Contains no more than 120 mcg/L
of aluminum.
Store at 20°C to 25°C (68°F to 77°F).
[See USP Controlled Room Temperature]. Avoid
excessive heat. Protect from freezing. If
accidentally frozen, discard the vial.



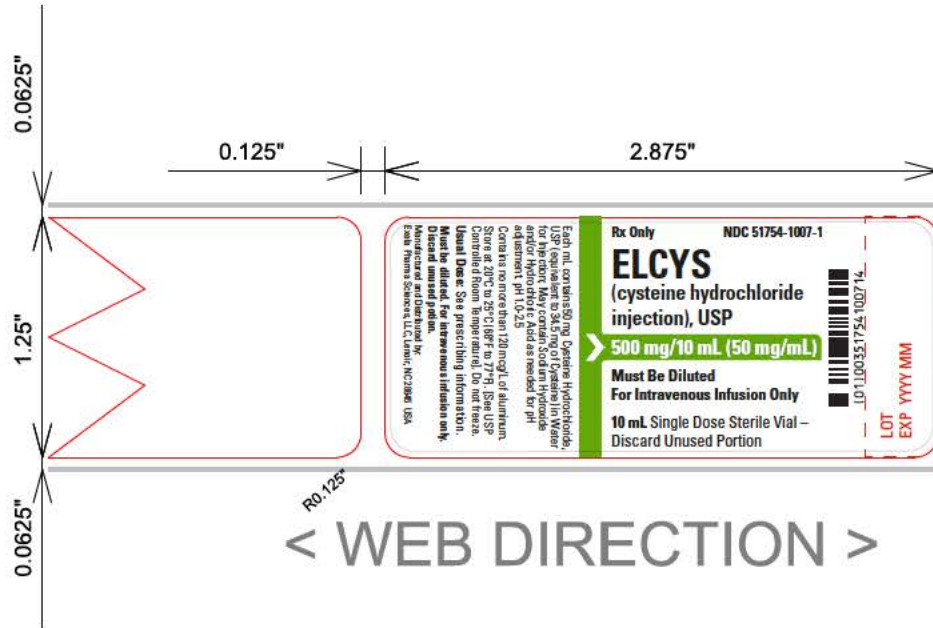
Manufactured and Distributed by:
Exela Pharma Sciences, LLC
Lenoir, NC 28645 USA



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ELCYS Injection, USP Vial

Round 9: 4-03-19 by (b) (4)



< WEB DIRECTION >



(b) (4)

Reference ID: 4420190

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LISA M SOULE
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