CARBAGLU®
(carglumic acid) tablet for oral suspension

Initial U.S. Approval: 2010

RECENT MAJOR CHANGES

Dosage and Administration (2) 11/2017
Warnings and Precautions (5.1) 11/2017

INDICATIONS AND USAGE

CARBAGLU is a Carbamoyl Phosphate Synthetase 1 (CPS 1) activator indicated as:

1. Acute Hyperammonemia in Patients with NAGS Deficiency
   - The recommended initial pediatric and adult dosage is 100 mg/kg/day to 250 mg/kg/day. Titrate based on plasma ammonia level and clinical symptoms.

2. Chronic Hyperammonemia in Patients with NAGS Deficiency
   - Maintenance therapy for the treatment of chronic hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS). (1.2)

DOSAGE AND ADMINISTRATION

1. Acute Hyperammonemia: The recommended initial pediatric and adult dosage is 100 mg/kg/day to 250 mg/kg/day. Titrate based on plasma ammonia level and clinical symptoms.

2. Chronic Hyperammonemia: The recommended pediatric and adult maintenance dosage is 10 mg/kg/day to 100 mg/kg/day. Titrate to target normal plasma ammonia level for age.

- Divide the total daily dose into two to four doses.

PREPARATION AND ADMINISTRATION

1. Preparation:
   - For all preparations, use in foods or liquids, other than water, has not been studied clinically and is not recommended.
   - CARBAGLU tablets do not dissolve completely in water and undissolved particles of the tablet may remain in the mixing container.
   - CARBAGLU tablets do not dissolve completely in water and undissolved particles of the tablet may remain in the catheter-tip syringe or NG tube.

2. Administration:
   - Take CARBAGLU immediately before meals or feedings.
   - CARBAGLU tablets do not dissolve completely in water and undissolved particles of the tablet may remain in the catheter-tip syringe or NG tube.

ADVERSE REACTIONS

Most common adverse reactions (>9%) are: vomiting, abdominal pain, pyrexia, tonsillitis, anemia, diarrhea, ear infection, infections, nasopharyngitis, hemoglobin decreased, and headache (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Recordati Rare Diseases Inc. at 1-888-575-8344, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

1.1 Acute Hyperammonemia in Patients with NAGS Deficiency
   - CARBAGLU is indicated as an adjunctive therapy in pediatric and adult patients for the treatment of acute hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS). During acute hyperammonemic episodes, concomitant administration of CARBAGLU with other ammonia lowering therapies, such as alternate pathway medications, hemodialysis, and dietary protein restriction, is recommended.

1.2 Chronic Hyperammonemia in Patients with NAGS Deficiency
   - CARBAGLU is indicated as maintenance therapy in pediatric and adult patients for the treatment of chronic hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS). During maintenance therapy, the concomitant administration of other ammonia lowering therapies and protein restriction may be needed based on plasma ammonia levels.

2.1 Recommended Dosage
   - CARBAGLU should be initiated as soon as the diagnosis of NAGS deficiency is suspected, which may be as soon as at birth, and managed by a physician and medical team experienced in metabolic disorders.

   - Initial Dosage: The recommended initial daily dosage of CARBAGLU in pediatric and adult patients for acute hyperammonemia is 100 mg/kg to 250 mg/kg divided into 2 to 4 doses and rounded to the nearest 100 mg (i.e., half of a CARBAGLU tablet). Concomitant administration of other ammonia lowering therapies is recommended.

   - Maintenance Dosage: The recommended daily maintenance dosage of CARBAGLU in pediatric and adult patients is 10 mg/kg to 100 mg/kg divided into 2 to 4 doses and rounded to the nearest 100 mg (i.e., half of a CARBAGLU tablet).

   - Therapeutic Monitoring
     - Closely monitor plasma ammonia levels. Titrate the CARBAGLU dosage to maintain the plasma ammonia level within the normal range for the patient’s age, taking into consideration their clinical condition (e.g., nutritional requirements, protein intake, growth parameters, etc.).

   - Monitor plasma ammonia and adjust the dosage to maintain the level within the normal range for age.

2.2 Preparation and Administration
   - Disperse CARBAGLU tablets in water. Do not swallow whole or crushed.
   - Mix each 200 mg tablet in a minimum of 2.5 mL of water to yield a concentration of 80 mg/mL.
   - CARBAGLU tablets do not dissolve completely in water and undissolved particles of the tablet may remain in the mixing container.
   - Take CARBAGLU immediately before meals or feedings.
   - The CARBAGLU suspension has a slightly acidic taste.

   - For all preparations, use in foods or liquids, other than water, has not been studied clinically and is not recommended.

Preparation for Oral Administration in Pediatric and Adult Patients
   - Add about 2.5 mL of water into a small cup for each CARBAGLU tablet or each ½ CARBAGLU tablet needed for the prescribed dose.
   - Add the CARBAGLU tablets to the water in the cup.
   - Carefully stir the tablet and water mixture.
   - Swallow the mixture immediately. Pieces of the tablet may remain in the cup.
   - Rinse the cup with additional water and swallow the mixture immediately. Repeat as needed until no pieces of the tablet are left in the cup.

Preparation for Nasogastric Tube Administration in Pediatric and Adult Patients
   - For patients who have a nasogastric tube in place, CARBAGLU should be administered as follows:
   - Add about 2.5 mL of water into a small cup for each CARBAGLU tablet or each ½ CARBAGLU tablet needed for the prescribed dose.
   - Add the CARBAGLU tablets to the water in the cup.
   - Carefully stir the tablet and water mixture.
   - Draw up the mixture into a catheter-tip syringe.
   - Administer the mixture immediately through the nasogastric (NG) tube. Pieces of the tablet may remain in the catheter-tip syringe or NG tube.

8.1 Pregnancy
8.4 Pediatric Use
8.5 Geriatric Use

ADVERSE REACTIONS

Most common adverse reactions (>9%) are: vomiting, abdominal pain, pyrexia, tonsillitis, anemia, diarrhea, ear infection, infections, nasopharyngitis, hemoglobin decreased, and headache (6.1).

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   - Therapeutic Monitoring
     - Closely monitor plasma ammonia levels. Titrate the CARBAGLU dosage to maintain the plasma ammonia level within the normal range for the patient’s age, taking into consideration their clinical condition (e.g., nutritional requirements, protein intake, growth parameters, etc.).

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   - Swallow the mixture immediately. Pieces of the tablet may remain in the cup.
   - Rinse the cup with additional water and swallow the mixture immediately. Repeat as needed until no pieces of the tablet are left in the cup.

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   - For patients who have a nasogastric tube in place, CARBAGLU should be administered as follows:
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   - Add the CARBAGLU tablets to the water in the cup.
   - Carefully stir the tablet and water mixture.
   - Draw up the mixture into a catheter-tip syringe.
   - Administer the mixture immediately through the nasogastric (NG) tube. Pieces of the tablet may remain in the catheter-tip syringe or NG tube.
There are no adequate and well controlled studies or available human data with CARBAGLU in pregnant women. Decreased survival and growth occurred in offspring born to animals treated with carglumic acid at a dose approximately 38 times the maximum reported in pregnant women. Decreased survival and growth occurred in offspring born to animals treated with carglumic acid at a dose approximately 38 times the maximum reported human maintenance dose [100 mg/kg/day] based on AUC (area under the plasma concentration-time curve) from two weeks prior to mating through organogenesis or in pregnant rabbits treated with up to 1000 mg/kg/day (approximately 6 times the maximum reported human maintenance dose [100 mg/kg/day] based on AUC). In a peri- and post-natal developmental study, female rats received oral caraglumic acid from organogenesis through lactation at doses of 500 and 2000 mg/kg/day. Decreased growth of offspring was observed at 500 mg/kg/day and higher (approximately 38 times the maximum reported human maintenance dose [100 mg/kg/day] based on AUC) and reduction in offspring survival during lactation was observed at 2000 mg/kg/day (approximately 38 times the maximum reported human maintenance dose [100 mg/kg/day] based on AUC). No effects on physical and sexual development, learning and memory, or reproductive performance were observed through maturation of the surviving offspring at maternal doses up to 2000 mg/kg/day. The high dose (2000 mg/kg/day) produced maternal toxicity (impaired weight gain and approximately 10% mortality).

6.3 Nursing Mothers
It is not known whether CARBAGLU is excreted in human milk. Carglumic acid is excreted in rat milk, and an increase in mortality and impairment of body weight gain occurred in neonatal rats nursed by mothers receiving caraglumic acid. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from CARBAGLU, breast-feeding is not recommended. Treatment is continuous and life-long for NAGS deficiency patients.

8.4 Pediatric Use
The efficacy of CARBAGLU for the treatment of hyperammonemia in patients with NAGS deficiency from birth to adulthood was evaluated in a retrospective review of the clinical course of 23 NAGS deficiency patients who all began CARBAGLU treatment during infancy or childhood. There are no apparent differences in clinical response between adults and pediatric NAGS deficiency patients treated with CARBAGLU. However, data are limited.

8.5 Geriatric Use
CARBAGLU has not been studied in the geriatric population. Therefore, the safety and effectiveness in geriatric patients have not been established.

10.1 Mechanism of Action
Carglumic acid is a synthetic structural analogue of N-acetylglutamate (NAG) which is produced from glutamate and acetyl-CoA in a reaction catalyzed by N-acetylglutamate synthase (NAGS), a mitochondrial liver enzyme. NAG acts as an essential allosteric activator of Carbamoyl Phosphate Synthetase 1 (CPS 1) activator and is soluble in boiling water, slightly soluble in cold water, and practically insoluble in organic solvents. Chemically, carglumic acid is N-carbamoyl-β-glutamic acid or (2S)-2-(carbamoylamino) pentanedioic acid, with a molecular weight of 190.16.

11 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
The pharmacokinetics of carglumic acid have been studied in healthy male subjects using both radiolabeled and non-radiolabeled carglumic acid.

Molecular Formula: C2H3N2O5
The inactive ingredients of CARBAGLU are croscarmellose sodium, hypromellose, microcrystalline cellulose, silica colloidal anhydrous, sodium lauryl sulfate, sodium stearyl fumarate.
Absorption
The median T<sub>max</sub> of CARBAGLU was 3 hours (range: 2 to 4 hours). Absolute bioavailability has not been determined.

Distribution
The apparent volume of distribution was 2657 L (range: 1616-5797). Protein binding has not been determined.

Elimination
A proportion of carglumic acid may be metabolized by the intestinal bacterial flora. The likely end product of carglumic acid metabolism is carbon dioxide, eliminated through the lungs.

Excretion
Median value for the terminal half-life was 5.6 hours (range 4.3 to 9.5 hours), the apparent total clearance was 5.7 L/min (range 3.0 to 9.7 L/min), the renal clearance was 290 mL/min (range 204 to 445 mL/min), and the 24-hour urinary excretion was 4.5% of the dose (range 3.5 to 7.5%). Following administration of a single radiolabeled oral dose of 100 mg/kg of body weight, 9% of the dose was excreted unchanged in the urine and up to 60% of the dose was excreted unchanged in the feces.

Drug Interaction Studies
No drug interaction studies have been performed. Based on in vitro studies, CARBAGLU is not an inducer of CYP1A1/2, CYP2B6, CYP2C, and CYP3A4/5 enzymes, and not an inhibitor of CYP1A2, CYP2A6, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6, CYP2E1, and CYP3A4/5 enzymes.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
The carcinogenic potential of carglumic acid was assessed in a 2-year carcinogenicity study in rats. Carglumic acid was not tumorigenic at oral doses up to 1000 mg/kg/day (approximately 34 times the maximum reported human maintenance dose [100 mg/kg/day] based on AUC).

Carglumic acid was negative in the Ames test, chromosomal aberration assay in human lymphocytes, and the in vivo micronucleus assay in rats.

There were no effects on fertility or reproductive performance in female rats at oral doses up to 2000 mg/kg/day (approximately 38 times the maximum reported human maintenance dose [100 mg/kg/day] based on AUC). In a separate study, mating and fertility were unaffected in male rats at oral doses up to 1000 mg/kg/day (approximately 34 times the maximum reported human maintenance dose [100 mg/kg/day] based on AUC).

14 CLINICAL STUDIES

14.1 Responses of Patients with NAGS Deficiency to Acute and Chronic Treatment
The efficacy of CARBAGLU in the treatment of hyperammonemia due to NAGS deficiency was evaluated in a retrospective review of the clinical course of 23 NAGS deficiency patients who received CARBAGLU treatment for a median of 7.9 years (range 0.6 to 20.9 years). Treatment with CARBAGLU was divided in two regimens. For acute treatment, patients received a total daily dose of 100 to 250 mg/kg per day primarily administered in 2 to 4 divided doses for the first few days of treatment. For maintenance treatment, the dosage was reduced over time based upon biochemical and clinical responses.

The demographics characteristics of the patient population are shown in Table 2.

Table 2. Baseline Characteristics of the 23 NAGS deficiency patients

<table>
<thead>
<tr>
<th>Gender</th>
<th>Male</th>
<th>N = 14 (61%)</th>
<th>Female</th>
<th>N = 9 (39%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at initiation of CARBAGLU therapy (years)</td>
<td>Mean (SD)</td>
<td>2 (4)</td>
<td>Min-Max</td>
<td>0-13</td>
</tr>
<tr>
<td>&lt; 30 days</td>
<td>9 (39%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥30 days - 11 months</td>
<td>9 (39%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥1 - 13 years</td>
<td>5 (22%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Homozygous</td>
<td>14 (61%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterozygous</td>
<td>4 (17%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not available</td>
<td>5 (22%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients current treatment status</td>
<td>On-going</td>
<td>18 (78%)</td>
<td>Discontinued</td>
<td>5 (22%)</td>
</tr>
</tbody>
</table>

The clinical observations in the 23 patient case series were retrospective, unblinded and uncontrolled and preclude any meaningful formal statistical analyses of the data. However, short-term efficacy was evaluated using mean and median change in plasma ammonia levels from baseline to days 1 to 3. Persistence of efficacy was evaluated using long-term mean and median change in plasma ammonia level. Table 3 summarizes the plasma ammonia levels at baseline, days 1 to 3 post-CARBAGLU treatment, and long-term CARBAGLU treatment for 13 evaluable patients. Of the 23 NAGS deficiency patients who received treatment with CARBAGLU, a subset of 13 patients who had both well documented plasma ammonia levels prior to CARBAGLU treatment and after long-term treatment with CARBAGLU were selected for analysis.

All 13 patients had abnormal ammonia levels at baseline. The overall mean baseline plasma ammonia level was 271 micromol/L. By day 3, normal plasma ammonia levels were attained in patients for whom data were available. Long-term efficacy was measured using the last reported plasma ammonia level for each of the 13 patients analyzed (median length of treatment was 6 years; range 1 to 16 years). The mean and median ammonia levels were 23 micromol/L and 24 micromol/L, respectively, after a mean treatment duration of 8 years.

Table 3. Plasma ammonia levels at baseline and after treatment with CARBAGLU

<table>
<thead>
<tr>
<th>Timepoint</th>
<th>Statistics (N = 13)</th>
<th>Ammonia** (micromol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>Mean (SD)</td>
<td>271 (359)</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>157</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>72-142</td>
</tr>
<tr>
<td></td>
<td>Missing Data</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>181 (358)</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>65</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>25-1190</td>
</tr>
<tr>
<td></td>
<td>Missing Data</td>
<td>3</td>
</tr>
<tr>
<td>Day 1</td>
<td>Mean (SD)</td>
<td>69 (78)</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>44</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>11-255</td>
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<tr>
<td></td>
<td>Missing Data</td>
<td>5</td>
</tr>
<tr>
<td>Day 2</td>
<td>Mean (SD)</td>
<td>27 (11)</td>
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<tr>
<td></td>
<td>Median</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>12-42</td>
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<tr>
<td></td>
<td>Missing Data</td>
<td>8</td>
</tr>
<tr>
<td>Day 3</td>
<td>Mean (SD)</td>
<td>23 (7)</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>9-34</td>
</tr>
<tr>
<td></td>
<td>Missing Data</td>
<td>0</td>
</tr>
</tbody>
</table>

* 13/23 patients with complete short-term and long-term plasma ammonia documentation
** Mean ammonia normal range: 5 to 50 micromol/L

The mean plasma ammonia level at baseline and the decline that is observed after treatment with CARBAGLU in 13 evaluable patients with NAGS deficiency is illustrated in Figure 1.

Figure 1: Ammonia response for 13 evaluable NAGS deficiency patients at baseline and after treatment with CARBAGLU

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied
CARBAGLU is a white and elongated 200 mg tablet for oral suspension, functionally scored and coded “C” on one side.

CARBAGLU is available in 5 or 60 tablets in a high density polyethylene bottle with child resistant polypropylene cap and desiccant unit.

NDC 52276-312-05 Bottles of 5 tablets
NDC 52276-312-60 Bottles of 60 tablets

Storage
Store in the original unopened container at 2 – 8°C (36 – 46°F).

After first opening of the container:
• Do not refrigerate, store at room temperature between 15 – 30°C (59 – 86°F).
• Keep the container tightly closed between openings in order to protect from moisture.
• Write the date of opening on the tablet container.
• Do not use after the expiration date stated on the tablet container.
• Discard one month after first opening.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Instructions for Use).

Preparation and Administration
• Disperse CARBAGLU tablets in water. Do not swallow whole or crushed.
• Take CARBAGLU immediately before meals or feedings.
• Do not refrigerate, store at room temperature between 15 – 30°C (59 – 86°F).

CARBAGLU tablets dispersed in water can be administered orally or via a nasogastric tube, as described in the Instructions for Use.
Storage
• Store UNOPENED container in a refrigerator at 2 to 8°C (36 to 46°F). After first opening of the container: do not refrigerate, store at room temperature between 15 to 30°C (59 to 86°F). Keep the container tightly closed in order to protect from moisture. Write the date of opening on the tablet container. Discard one month after first opening. Do not use after the expiration date stated on the tablet container.

Lactation
• Advise women not to breast-feed during treatment with CARBAGLU [see Use in Specific Populations (8.3)].

Supplied by:
Orphan Europe SARL
Puteaux, France

Licensed to and Distributed by:
Recordati Rare Diseases Inc.
Lebanon, NJ 08833

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This product label may have been updated. For the most recent prescribing information, please visit www.recordatirarediseases.com or www.carbaglu.net.
INSTRUCTIONS FOR USE
CARBAGLU (CAR-buh-gloo)
carglumic acid
tablet for oral suspension

Important information:
• CARBAGLU tablet for oral suspension (CARBAGLU tablet) must be mixed in water before taking. CARBAGLU tablets should not be mixed in any other food or liquid.
• Do not swallow CARBAGLU tablets whole.
• Do not crush CARBAGLU tablets.
• Take CARBAGLU right before meals or feedings.
• The CARBAGLU tablet and water mixture has a slightly sour taste.

You may need to ask your healthcare provider or pharmacist for a medicine cup to measure the correct amount of water you will need to prepare your dose of CARBAGLU.

Taking CARBAGLU tablets by mouth using a cup:

Children and Adults
1. Add about 2.5 mL of water into a small cup for each CARBAGLU tablet, or each ½ CARBAGLU tablet, needed for the prescribed dose. For example, if the prescribed dose is 2 CARBAGLU tablets, add about 5 mL of water into the cup. If the prescribed dose is 2½ CARBAGLU tablets, add about 7.5 mL of water into the cup. Ask your healthcare provider if you are not sure of how much water you should use for the prescribed dose of CARBAGLU.
2. Place the prescribed number of CARBAGLU tablets into the water in the cup.
3. Carefully stir the CARBAGLU tablet and water mixture in the cup to avoid spilling the mixture. CARBAGLU tablets do not dissolve completely in water.
4. Swallow the CARBAGLU tablet and water mixture right away.
5. Pieces of the tablet may remain in the cup. Add more water to the cup to rinse the cup and swallow the mixture right away.
6. Repeat step 5 until there are no pieces of the tablet left in the cup.

Taking CARBAGLU tablets by mouth using an oral syringe:

Children
1. Add about 2.5 mL of water into a small cup for each CARBAGLU tablet, or each ½ CARBAGLU tablet, needed for the prescribed dose. For example, if the prescribed dose is 2 CARBAGLU tablets, add about 5 mL of water into the cup. If the prescribed dose is 2½ CARBAGLU tablets, add about 7.5 mL of water into the cup. Ask your healthcare provider if you are not sure of how much water you should use for the prescribed dose of CARBAGLU.
2. Place the prescribed number of CARBAGLU tablets into the water in the cup.
3. Carefully stir the CARBAGLU tablet and water mixture in the cup to avoid spilling the mixture. CARBAGLU tablets do not dissolve completely in water.
4. Draw up all of the CARBAGLU tablet and water mixture in the cup into a catheter-tip syringe.
5. Connect the catheter-tip syringe to the NG tube.
6. Give the CARBAGLU tablet and water mixture through the NG tube right away.
7. Pieces of the tablet may remain in the catheter-tip syringe or NG tube. Refill the catheter-tip syringe with 1 mL to 2 mL of water and flush the NG tube right away.
8. Repeat step 7 until there are no pieces of the tablet left in the catheter-tip syringe or NG tube.

Giving CARBAGLU tablets through a nasogastric (NG) tube:

Children and Adults
1. Add about 2.5 mL of water into a small cup for each CARBAGLU tablet, or each ½ CARBAGLU tablet, needed for the prescribed dose. For example, if the prescribed dose is 2 CARBAGLU tablets, add about 5 mL of water into the cup. If the prescribed dose is 2½ CARBAGLU tablets, add about 7.5 mL of water into the cup. Ask your healthcare provider if you are not sure of how much water you should use for the prescribed dose of CARBAGLU.
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4. Draw up all of the CARBAGLU tablet and water mixture in the cup into a catheter-tip syringe.
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6. Give the CARBAGLU tablet and water mixture through the NG tube right away.
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8. Repeat step 7 until there are no pieces of the tablet left in the catheter-tip syringe or NG tube.

How should I store CARBAGLU?
• Before opening, store CARBAGLU in a refrigerator between 36°F to 46°F (2°C to 8°C) in the container it comes in.
• After opening, store CARBAGLU at room temperature between 59°F to 86°F (15°C to 30°C). Do not store CARBAGLU in a refrigerator.
  ○ Keep CARBAGLU tablets in a tightly closed container to protect the tablets from moisture.
  ○ Write the date the CARBAGLU tablet container is opened on the container label. Throw away any unused tablets one month after opening the tablet container.
• Do not use CARBAGLU tablets after the expiration date on the tablet container.

Keep CARBAGLU and all medicines out of the reach of children.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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