

Carbaglu[®]
(carglumic acid) tablets for oral suspension
200mg

How to Use and Store CARBAGLU

*For individuals with
NAGS deficiency*



Please see full Indication and Important Safety Information at www.CARBAGLU.com.

How to Take CARBAGLU®

CARBAGLU is a prescription drug used in all ages to help treat a rare inherited disorder called NAGS deficiency, a lack or shortage of NAGS enzyme activity, which leads to high blood ammonia levels (hyperammonemia). CARBAGLU is a white, elongated tablet that is scored and printed “C” on one side. Each tablet contains 200 mg of carglumic acid.

CARBAGLU is usually given for the first time in a hospital or emergency setting. Your initial dose will depend on your specific symptoms and ammonia level, as well as whether or not you have moderate or severe kidney problems. Your doctor may also recommend other therapies to help lower your ammonia levels.

After an initial phase of dose adjustment, you may be placed on a maintenance dose. This dose of CARBAGLU should be adjusted to target a normal blood ammonia level for your age.

Your total daily dose should be divided into 2 to 4 doses, rounded to the nearest 50 mg or 100 mg (1/4 or 1/2 of a CARBAGLU tablet) and taken right before meals or feedings. You can find this and additional information in the full Prescribing Information, including Instructions for Use. Always consult your doctor with questions about your prescribed dose of CARBAGLU.

Different Ways CARBAGLU Can Be Taken

There are three different ways that CARBAGLU can be taken, based on patient age and condition: by mouth, by mouth using an oral syringe, and through a nasogastric (NG) tube or gastrostomy tube (G-tube).

Important Information

- **CARBAGLU tablet for oral suspension 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 the dose of CARBAGLU.
- **The CARBAGLU tablet has 3 lines used for splitting the tablet into 4 equal parts in order to get the prescribed dose.** Ask your healthcare provider if you have any questions about how to split the tablet the right way or have any questions about the prescribed dose.

IMPORTANT SAFETY INFORMATION

- Most common side effects in $\geq 13\%$ of patients are: vomiting, abdominal pain, fever, inflammation of the tonsils, reduced red cells in the blood, diarrhea, ear infection, infections, inflammation of the throat and nasal passages, hemoglobin decreased in red blood cells, and headache.

Please visit www.CARBAGLU.com for full Prescribing Information, including Instructions for Use, and for more information about taking CARBAGLU.

Carbaglu®
(carglumic acid) tablets for oral suspension
200mg

By Mouth Using a Cup



Children and Adults

1. Add at least 2.5 mL of water into a small cup for each CARBAGLU tablet, or each $\frac{1}{2}$ or $\frac{1}{4}$ CARBAGLU tablet, needed for the prescribed dose. For example:
 - If the prescribed dose is 2 CARBAGLU tablets, add at least 5 mL of water into the cup.
 - If the prescribed dose is $2\frac{1}{4}$ CARBAGLU tablets, add at least 7.5 mL of water into the cup.
 - If the prescribed dose is $2\frac{1}{2}$ CARBAGLU tablets, add at least 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.

By Mouth Using an Oral Syringe



Children

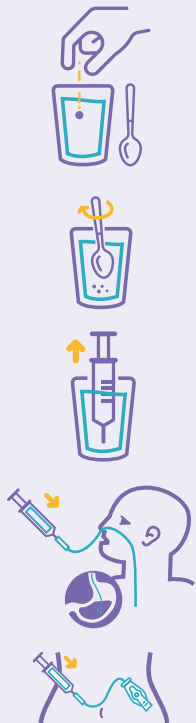
1. Add at least 2.5 mL of water into a small cup for each CARBAGLU tablet, or each $\frac{1}{2}$ or $\frac{1}{4}$ CARBAGLU tablet, needed for the prescribed dose. For example:
 - If the prescribed dose is 2 CARBAGLU tablets, add at least 5 mL of water into the cup.
 - If the prescribed dose is $2\frac{1}{4}$ CARBAGLU tablets, add at least 7.5 mL of water into the cup.
 - If the prescribed dose is $2\frac{1}{2}$ CARBAGLU tablets, add at least 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 an oral syringe.
5. Give your child the CARBAGLU tablet and water mixture **right away** by placing the tip of the oral syringe along the inner cheek of their mouth, on either the right or left side. Slowly push all the way down on the plunger to give the medicine.
6. Pieces of the tablet may remain in the oral syringe. Refill the oral syringe with at least 1 mL to 2 mL of water, and give your child the mixture **right away**.
7. Repeat step 6 until there are no pieces of the tablet left in the oral syringe.

Carbaglu[®]
(carglumic acid) tablets for oral suspension
200mg

Through a Nasogastric (NG) Tube or Gastrostomy Tube (G-tube)



Children and Adults

1. Add at least 2.5 mL of water into a small cup for each CARBAGLU tablet, or each $\frac{1}{2}$ or $\frac{1}{4}$ CARBAGLU tablet, needed for the prescribed dose. For example:
 - If the prescribed dose is 2 CARBAGLU tablets, add at least 5 mL of water into the cup.
 - If the prescribed dose is $2\frac{1}{4}$ CARBAGLU tablets, add at least 7.5 mL of water into the cup.
 - If the prescribed dose is $2\frac{1}{2}$ CARBAGLU tablets, add at least 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 or G-tube.
6. Give the CARBAGLU tablet and water mixture through the NG tube or G-tube **right away**.
7. Pieces of the tablet may remain in the catheter-tip syringe or NG tube or G-tube.
8. Refill the catheter-tip syringe with 1 mL to 2 mL of water and flush the NG tube or G-tube **right away**.
9. Repeat step 8 until there are no pieces of the tablet left in the catheter-tip syringe or NG tube or G-tube.

Storing CARBAGLU®



Before opening, store CARBAGLU in a refrigerator between 36°F to 46°F (2°C to 8°C) in the bottle it comes in.



After opening, store CARBAGLU at room temperature between 59°F to 86°F (15°C to 30°C). **Do not** store opened CARBAGLU in a refrigerator.



Keep the CARBAGLU bottle tightly closed to protect the tablets from moisture.



Write the date the CARBAGLU bottle is opened on the bottle label. Throw away any unused tablets one month after opening the tablet bottle.

Do not use CARBAGLU tablets after the expiration date on the bottle label.

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

Carbaglu®
(carglumic acid) tablets for oral suspension
200mg

INDICATIONS AND USAGE

CARBAGLU® (carglumic acid) tablets for oral suspension 200mg is a prescription drug used in all ages to help treat the following:

- CARBAGLU is used to supplement standard of care treatment for acute high blood ammonia levels (hyperammonemia) due to the lack or shortage of NAGS enzyme activity.
- CARBAGLU is used to maintain normal blood ammonia levels due to the lack or shortage of NAGS enzyme activity.

IMPORTANT SAFETY INFORMATION

- Contraindications: None.
- Most common side effects in $\geq 13\%$ of patients are: vomiting, abdominal pain, fever, inflammation of the tonsils, reduced red cells in the blood, diarrhea, ear infection, infections, inflammation of the throat and nasal passages, hemoglobin decreased in red blood cells, and headache.
- **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.**

Please visit www.CARBAGLU.com for full Prescribing Information, including Instructions for Use, and for more information about taking CARBAGLU.

Obtaining CARBAGLU®

CARBAGLU is not available in retail pharmacies. Instead, it is available only through a specialty pharmacy called Accredo. Accredo will work with you and your insurance company and will mail your medication to your home.

Your doctor will send your CARBAGLU prescription and enrollment form to Accredo. Accredo may contact you if your insurance company needs additional information.

It is important to return all calls from Accredo so that you'll get your prescribed medication when you need it.

You can contact Accredo by calling 1-888-454-8860.

Financial Assistance Programs

For individuals experiencing financial hardship, Recordati Rare Diseases Inc. supports a Patient Assistance Program and a Co-Pay Assistance Program, administered by Accredo. For more information, call Accredo: 1-888-454-8860.

Please visit www.CARBAGLU.com for full Prescribing Information, including Instructions for Use, and for more information about taking **CARBAGLU**.



CARBAGLU is a licensed trademark of Recordati Rare Diseases Inc. Trademarks, registered or otherwise, are the property of their respective owner(s).

© 2024 Recordati Rare Diseases Inc.

www.recordatirarediseases.com/us PP-CBGL-US-0179v5

Carbaglu®
(carglumic acid) tablets for oral suspension
200mg