

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr CARBAGLU

Carglumic Acid Dispersible Tablets

Read this carefully before you start taking CARBAGLU and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about CARBAGLU.

What is CARBAGLU used for?

CARBAGLU is used in adults and children who are missing a liver enzyme called N acetylglutamate synthase (NAGS):

- to treat high ammonia in the blood. It may be used with other treatments. This includes: hemodialysis, other ammonia lowering medications, and a low protein diet.
- to maintain the blood ammonia at a normal level.

CARBAGLU is also used with other treatments to lower blood ammonia levels in adults and children having a hyperammonemia crisis (extremely high levels of ammonia in the blood) from conditions called propionic acidemia (PA) or methylmalonic acidemia (MMA).

How does CARBAGLU work?

CARBAGLU activates an enzyme in your liver to help remove ammonia from your blood. Ammonia is especially toxic for the brain. CARBAGLU lowers blood ammonia levels. This can help reduce or get rid of these toxic effects.

What are the ingredients in CARBAGLU?

Medicinal ingredients: carglumic acid

Non-medicinal ingredients: croscarmellose sodium, hypromellose, microcrystalline cellulose, silica colloidal anhydrous, sodium lauryl sulfate, sodium stearyl fumarate

CARBAGLU comes in the following dosage forms:

Dispersible tablet, 200 mg

The tablet can be divided into equal portions.

Do not use CARBAGLU if:

- you are allergic to carglumic acid or any of the non-medicinal ingredients or components of the container (see **What are the ingredients in CARBAGLU?**)
- you are breastfeeding

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CARBAGLU. Talk about any health conditions or problems you may have, including if you:

- have kidney problems
- are pregnant or planning to become pregnant

Other warnings you should know about:

Treatment with CARBAGLU will be started under the care of a healthcare professional specialized in your condition. Your dose will be adjusted by your healthcare professional to keep your blood ammonia levels normal.

Episodes of high ammonia blood levels: Your blood ammonia levels can quickly increase. If you have high ammonia blood levels, you should receive treatment immediately. Ammonia is toxic, especially to the brain. It can lead to reduced consciousness and coma, when blood ammonia levels are high. During episodes of high ammonia blood levels, your healthcare professional will tell you what to do. Your healthcare professional may tell you to increase your calories and not to eat protein. When your ammonia level is back to normal, your healthcare professional will tell you if you can eat protein again or if you should continue to restrict your protein intake.

Monitoring and blood tests: Your healthcare professional will check your liver, kidneys, and heart regularly. This is to ensure they are working properly. They will also monitor your mental status, protein intake and general nutrition. Children taking CARBAGLU will also have their growth and development monitored. CARBAGLU can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results. Your healthcare professional will make sure CARBAGLU is helping you and not causing harmful effects.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with CARBAGLU:

- medicines used to treat epilepsy, such as carbamazepine, phenobarbital, topiramate, and valproate
- corticosteroids, used to treat inflammation and suppress the immune system
- haloperidol, used to treat mental health problems

How to take CARBAGLU:

- The daily dose of CARBAGLU should be divided into two to four doses.
- Take CARBAGLU before meals or feedings.
- Do NOT crush or swallow CARBAGLU whole.
- Always mix CARBAGLU in a minimum of 2.5 mL of water. CARBAGLU tablets do not dissolve completely in water. Part of the tablet may stay in the mixing container.
- The mixture has a slightly acidic taste.
- By Mouth:
 - o swallow CARBAGLU immediately once you mix it with water
 - o rinse the container with more water
 - o swallow this extra water immediately as part of your dose
- By Mouth using an Oral Syringe for Pediatric Patients
 - o Mix CARBAGLU in 2.5 mL of water. Shake gently to dissolve
 - o Fill up oral syringe with mixture and administer immediately
 - o Refill syringe with water (minimum 1-2 mL) and administer immediately
 - o Repeat until no pieces are left in the syringe.
- By Nasogastric/Gastrostomy Tube:
 - o give CARBAGLU immediately once you mix it with water
 - o give it by fast push through a syringe
 - o flush with additional water to clear the nasogastric tube

Usual dose:

Your healthcare professional will determine the dose that is right for you based on your weight and the level of ammonia in your blood. Do not change your dose without talking to your healthcare professional.

Overdose:

If you think you, or a person you are caring for, have taken too much CARBAGLU, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

You may have the following symptoms if you have taken too much CARBAGLU; rapid heartbeat, heavy sweating, coughing up mucous, high body temperature and feeling restless.

Missed Dose:

If you have forgotten a dose, skip the missed dose and continue to take your next dose at the regularly scheduled time. Do not take a double dose to make up for a forgotten dose.

What are possible side effects from using CARBAGLU?

These are not all the possible side effects you may have when taking CARBAGLU. If you experience any side effects not listed here, tell your healthcare professional.

- fever
- diarrhea, stomach pain
- inflammation of the tonsils, ear infections, nose and throat infections, other infections
- headache

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Anemia (decreased number of red blood cells): fatigue, loss of energy, looking pale, shortness of breath, weakness		✓	
Apnea : stop breathing for short periods			✓
Drowsiness	✓		
Encephalopathy (brain dysfunction): agitation, change in mental state, confusion, difficulty thinking, disorientation, going in and out of consciousness, hallucinations, sudden involuntary muscle jerks, tremors or twitches			✓
Enterocolitis infection (inflammation of the digestive tract): fever, diarrhea, nausea, vomiting, stomach cramps or pain, loss of appetite		✓	
Pneumonia (infection in the lungs): chest pain when you breath or cough, confusion, cough which may produce phlegm, fatigue, sweating and shaking chills, nausea, shortness of breath			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Seizures (fit): uncontrollable shaking with or without loss of consciousness			✓
Vomiting	✓		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep out of reach and sight of children.

Keep CARBAGLU in the fridge (2 - 8°C).

After first opening the tablet container:

- Keep the container tightly closed in order to protect from moisture.
- Discard one month after first opening.

If you want more information about CARBAGLU:

- Talk to your healthcare professional

- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website <https://www.recordatirarediseases.com/ca/products>, or by calling 1-877-827-1306.

This leaflet was prepared by Recordati Rare Diseases Canada Inc.

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