

PART III: CONSUMER INFORMATION**CARBAGLU®**

Carglumic acid dispersible tablets

This leaflet is part III of a three-part "Product Monograph" published when CARBAGLU was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CARBAGLU. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

CARBAGLU is used if you are missing a liver enzyme called N-acetylglutamate synthase (NAGS) or have hyperammonemia crisis (extremely high levels of ammonia in the blood) from conditions called propionic acidemia (PA) or methylmalonic acidemia (MMA):

- To treat high ammonia in the blood. It may be used with other therapies as discussed with your doctor. This includes a low protein diet
- To maintain your blood ammonia at a normal level

What it does:

CARBAGLU activates an enzyme in your liver to help remove ammonia from your blood. Ammonia is especially toxic for the brain. CARBAGLU reduces blood ammonia levels and can help reduce or eliminate these toxic effects.

When it should not be used:

Do not take CARBAGLU if you are:

- allergic to this drug or to any of its ingredients

Do not breastfeed while taking CARBAGLU.

What the medicinal ingredient is:

Carglumic acid.

What the important nonmedicinal ingredients are:

Croscarmellose sodium, hypromellose, microcrystalline cellulose, silica colloidal anhydrous, sodium lauryl sulfate, sodium stearyl fumarate.

What dosage forms it comes in:

Dispersible tablet, 200 mg.

The tablet can be divided into equal portions.

WARNINGS AND PRECAUTIONS

Episodes of high ammonia blood level with rapid start should be treated immediately. Ammonia is toxic especially to the brain. It

can lead to reduced consciousness and coma.

Treatment should be started under care of a doctor specialized in your condition. Dose will be adjusted by your doctor to keep your ammonia blood levels normal.

During episodes of high ammonia blood levels, your doctor will tell you what to do. Your doctor may tell you to increase your calories and not to eat protein for 1 or 2 days. When your ammonia level is back to normal, your doctor will tell you if you can eat protein again or restrict your protein intake.

Your doctor will examine your liver, kidney, heart, and blood regularly. He will make sure CARBAGLU is helping you and not causing harmful effects.

If you are pregnant and taking CARBAGLU, consult your doctor.

INTERACTIONS WITH THIS MEDICATION

CARBAGLU can react with other drugs. Tell your doctor about all the drugs you take. Include those prescribed by other doctors. Report your use of vitamins, minerals, natural or alternative medicines.

The following may interact with CARBAGLU by raising the blood ammonia levels:

- Drugs that treat epilepsy. These include valproate, carbamazepine, phenobarbital and topiramate
- Corticosteroids
- Haloperidol

PROPER USE OF THIS MEDICATION

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.

By Mouth:

- swallow CARBAGLU immediately once you mix it with water
- rinse the container with more water
- swallow this extra water immediately as part of your dose

By Nasogastric/Gastrostomy Tube:

- give CARBAGLU immediately once you mix it with water
- give it by fast push through a syringe
- flush with additional water to clear the nasogastric tube.

The mixture has a slightly acidic taste.

Usual Dose:

Your doctor will determine the dose based on your weight and the level of ammonia in your blood. Do not change your dose without checking with your doctor or pharmacist.

NAGS Deficiency

Divide the total daily amount of CARBAGLU into two to four doses as prescribed by your doctor.

Usual Initial Daily Dose: 100 mg/kg/day, up to 250 mg/kg/day if necessary.

Daily Maintenance Dose: is individualized for each patient. It ranges from 10 mg/kg/day to 100 mg/kg/day.

PA and MMA

Divide the total daily amount of CARBAGLU into two doses as prescribed by your doctor.

Usual Daily Dose: 150 mg/kg/day taken 12 hours apart for up to 7 days.

Your doctor may prescribe a different dose for you based on your health situation. Always follow the dose prescribed by your doctor.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Do not wait for any signs or symptoms to appear before seeking medical attention, as they may not occur immediately.

In a case of overdose, the following symptoms were observed: rapid heartbeat, heavy sweating, coughing up mucous, fever and feeling restless. These symptoms stopped when the dose was decreased.

Missed Dose:

Do not take a double dose to make up for forgotten individual doses. If you have forgotten a dose, continue to take the next dose at the regularly scheduled time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effects associated with CARBAGLU are:

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

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency help
	Only if severe	In all cases	
Common			
Vomiting	✓		
Drowsiness	✓		
Seizures			✓
Apnea (stop breathing for short periods)			✓
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			✓
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		✓	

Some of these side effects may be temporary. Others may be serious or dose-related. Consult your doctor if you experience these or any other side effects.

CARBAGLU can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

This is not a complete list of side effects. For any unexpected effects while taking CARBAGLU, contact your doctor or pharmacist.

HOW TO STORE IT

Keep out of the reach of children.

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

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

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected side effect associated with the use of health products to the 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 effect(s). The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for healthcare professionals, can be found at <https://www.recordatirarediseases.com/ca/products> or by contacting Recordati Rare Diseases Canada Inc. at 1-877-827-1306:

This leaflet was prepared by:
Recordati Rare Diseases Canada Inc.
Toronto, ON, M4N 3N1

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