

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:**

Use Carbaglu if you are missing a liver enzyme called N-acetylglutamate synthase (NAGS):

- 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:

Patients with NAGS deficiency lack a liver enzyme. It normally helps break down ammonia that builds up in the blood after eating protein. This is toxic to the body and especially to the brain. Carbaglu activates an enzyme that breaks down ammonia. It reduces blood ammonia levels and its 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 nonmedicinal ingredients are:

Croscarmellose sodium, hypromellose, microcrystalline cellulose, silica colloidal anhydrous, sodium laurilsulfate, 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. He 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. You may have to take arginine supplements 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 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.

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.

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:

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

Carbaglu can cause some serious side effects such as pneumonia, drowsiness and vomiting.

It can also cause some serious side effects such as pneumonia, drowsiness, and vomiting.

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).

After first opening the tablet container:

- 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 adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals, can be found by contacting Recordati Rare Diseases Inc. at:

Recordati Rare Diseases Inc.:
1215 North Service Rd. W., Unit "B"
Oakville, ON, L6M 2W2
Tel: 905.827.1300
Fax: 905.825.9292

Last revised: April 5, 2017