

CARBAGLU®

Carglumic acid, 200 mg Dispersible Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the more common questions about Carbaglu.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Carbaglu against the benefits he/she expects it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read this again.

What CARBAGLU is used for

Carbaglu is used to eliminate excessive levels of ammonia, referred to as hyperammonaemia. The high levels of ammonia in the blood may be caused by the lack of a specific liver enzyme called N-acetyl glutamate synthase (NAGS) or due to isovaleric acidaemia, methylmalonic acidaemia or propionic acidaemia.

High levels of ammonia in the blood are toxic for the brain and leads in severe cases, to reduced levels of consciousness and coma. Some people are born with inherited diseases that cause some of the body's enzymes to be missing or defective. The deficiency of NAGS is a rare disorder and results in patients not being able to eliminate nitrogen waste from the body which builds up after eating protein. This disorder persists for life and therefore the need for this treatment is lifelong.

Isovaleric acidaemia, methylmalonic acidaemia and propionic acidaemias are rare disorders that can inhibit NAGS and cause episodes of hyperammonaemia. The treatment of elevated ammonia in these disorders is required during these episodes. Carbaglu helps the body's natural process to eliminate ammonia by triggering the enzymes required to convert this to urea. This is eliminated from the body in urine.

Ask your doctor if you have any questions about why Carbaglu has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before your doctor gives you CARBAGLU

Tell your doctor if you:

- Have allergies to any medicines
- Are taking or using any other medicines. These include medicines bought from pharmacies, supermarkets and health food stores
- Have any other medical conditions
- Are pregnant or breast feeding.

If you want further information, consult your doctor.

How to take CARBAGLU

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

Your doctor may discuss with you the need to be on a restricted diet while you take Carbaglu.

If you do not understand the instructions, ask your doctor or pharmacist for help.

Your doctor will evaluate your individual responsiveness to Carbaglu before initiating any long term treatment.

The dose will be individually adjusted in order to maintain normal ammonia plasma levels.

Once the bottle containing the Carbaglu tablets has been opened, the tablets can be used for 3 months. Write the date when the bottle was first opened in the space provided on the bottle label.

How much to take

Each tablet contains 200mg.

The normal initial dose of Carbaglu is 100mg per kilogram of body weight per day. This dose may be increased to 250 mg per kilogram of body weight per day.

For patients suffering from NAGS deficiency, in the long term, the daily dose usually ranges from 10 mg to 100 mg per kilogram of body weight.

The total daily dose should be divided into 2 to 4 doses and round to the nearest 100 mg (half a Carbaglu tablet).

Your doctor may also recommend other therapies to help lower your ammonia levels.

Always consult your doctor with questions about your prescribed dose.

How to take it

Carbaglu tablets should not be swallowed whole or crushed.

Adults

Each 200 mg tablet should be dispersed in 5 to 10 ml of water and taken immediately.

Carbaglu tablets do not dissolve completely in water and undissolved particles of the tablet may remain in the mixing container. To ensure complete delivery of the dose, rinse the mixing container with additional volumes of water and swallow the contents immediately.

The suspension may taste slightly acidic.

Children

Each 200 mg tablet should be dispersed in a minimum of 2.5 ml of water. For swallowing using a syringe, draw up the volume of the liquid using an oral syringe and administer immediately. The syringe may be refilled with a small amount of water (1 – 2 mL) and administered.

For use with a nasogastric tube, the dose is given in the same way as above, with the tube flushed with water after administration.

When to take it

Carbaglu treatment should be initiated under the supervision of a doctor and given before meals or feeding.

How long to take it

Take Carbaglu for as long as your doctor tells you.

Carbaglu helps to lower your levels of ammonia in the blood, but it does not cure your condition.

If you forget to take it

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, talk to your doctor or pharmacist.

If you take too much of it (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Carbaglu. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking CARBAGLU

Things you must do

Your doctor may ask you to have your liver, kidney, heart functions and blood tested from time to time to make sure the medicine is working to prevent unwanted side effects.

Your blood ammonia levels also need to be checked regularly while you are taking this medicine.

If you become pregnant while you are taking Carbaglu, contact your doctor immediately.

If you are about to be started on any new medication, remind your doctor and pharmacist that you are taking Carbaglu.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

Things you must not do

Do not give Carbaglu to anyone else even if they have the same condition as you.

Do not take Carbaglu to treat any other complaints unless your doctor tell you.

Side Effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Increased sweating
- Slow heart beat
- Diarrhoea
- Abdominal Pain
- Fever or high temperature
- Vomiting.

After taking CARBAGLU

Storage

Keep your tablets in the container until it is time to take them.

If you take the tablets out of the bottle they may not keep well

Store the unopened bottle in a refrigerator. Do not freeze the tablets.

Once the tablet container has been opened, the opened bottle can be stored in a cool dry place out of direct sunlight.

The container must be used within 3 months of the container being opened.

Keep your tablets where children cannot reach them.

Disposal

If your doctor tells you to stop taking Carbaglu, or it has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

Product Description

What it looks like

Carbaglu dispersible tablets are a bar-shaped tablet, with 4 punches on one side and with 3 break-mark on both sides.

Carbaglu is supplied in two container sizes, one containing 5 tablets and the other containing 60 tablets. The tablets are stored in a re-sealable container.

Ingredients

The active ingredient of Carbaglu is carglumic acid.

The other ingredients are:

- microcrystalline cellulose
- sodium lauryl sulphate
- hypromellose
- croscarmellose sodium
- silica colloidal anhydrous
- sodium stearyl fumarate.

This medicine does not contain lactose or gluten.

Supplier

Carbaglu is supplied in Australia by:

Recordati Rare Diseases Australia, Pty. Ltd.
Level 6, 69 Reservoir Street,
Surry Hills,
Sydney NSW 2010, Australia

Email: RRD.Australia@recordati.com

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