

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Carbaglu?

Carbaglu contains the active ingredient carglumic acid. Carbaglu is used to eliminate excessive levels of ammonia, referred to as hyperammonaemia. For more information, see Section [1. Why am I using Carbaglu?](#) in the full CMI.

2. What should I know before I use Carbaglu?

Do not use if you have ever had an allergic reaction to Carbaglu or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Carbaglu?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Carbaglu and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Carbaglu?

- The normal initial dose of Carbaglu is 100mg per kilogram of body weight per day. This dose may be increased to 250mg per kilogram of body weight per day. Follow all directions given to you by your doctor and pharmacist carefully.
- Each 200mg Carbaglu tablet should be dispersed in 5 to 10 ml of water and taken immediately.

More instructions can be found in Section [4. How do I use Carbaglu?](#) in the full CMI.

5. What should I know while using Carbaglu?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Carbaglu.• If you become pregnant or are breast feeding while you are taking Carbaglu, contact your doctor immediately.• To make sure Carbaglu is working to prevent unwanted side effects, your doctor may ask you to have your liver, kidney and heart functions and blood tested from time to time. Your blood ammonia levels also need to be checked regularly while taking this medicine.• Tell your doctor if you have renal impairment. Your daily dose may need to be reduced.
Things you should not do	<ul style="list-style-type: none">• 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 tells you.
Driving or using machines	<ul style="list-style-type: none">• There is no information regarding any warnings to consider before driving or operating machinery.
Drinking alcohol	<ul style="list-style-type: none">• There is no information regarding drinking alcohol while using the medicine.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the container until it is time to take them. Keep the container tightly closed in order to protect from moisture.• Store the unopened bottle in the refrigerator at 2°C to 8°C. Do not freeze tablets.• Once the tablet container has been opened, it must be used within 3 months. Store the opened container in a cool dry place below 30°C (do not refrigerate) and out of direct sunlight.

For more information, see Section [5. What should I know while using Carbaglu?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them. Sometimes they are serious, most of the time they are not. More common side effects include vomiting and diarrhoea. Sign of a serious side effect is slowed heartbeat. You may need medical treatment if you get some of the side effects. Ask your doctor or pharmacist to answer any questions you may have.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Carbaglu[®]

Active ingredient: *Carglumic acid*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Carbaglu. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Carbaglu.**

Where to find information in this leaflet:

- [1. Why am I using Carbaglu?](#)
- [2. What should I know before I use Carbaglu?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Carbaglu?](#)
- [5. What should I know while using Carbaglu?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Carbaglu?

Carbaglu contains the active ingredient carglumic acid. 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.

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 a lack of a specific liver enzyme called N-acetyl glutamate synthase (NAGS), or due to isovaleric acidemia, methylmalonic acidemia or propionic acidemia.

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 acidemia, methylmalonic acidemia and propionic acidemias 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.

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

2. What should I know before I use Carbaglu?

Warnings

Do not use Carbaglu:

- if you are allergic to carglumic acid, or any of the ingredients listed at the end of this leaflet.
- to treat any other complaints unless your doctor tells you.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions, especially if you have renal impairment. Your daily dose may need to be reduced.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Carbaglu and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Carbaglu.

4. How do I use Carbaglu?

Follow all directions given to you by your doctor and pharmacist carefully. These directions may differ from the information contained in this leaflet. 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 adjusted in order to maintain normal ammonia plasma levels.

How much to take

- Each tablet contains 200mg.
- The normal initial dose of Carbaglu is 100mg per kilogram of body weight per day. The dose may be increased to 250mg per kilogram of body weight per day.
- For patients suffering from NAGS deficiency, in the long term, the daily dose usually ranges from 10mg to 100mg per kilogram of body weight. The total daily dose should be divided into 2 to 4 doses and round to the nearest 100mg (half a Carbaglu tablet).
- Your doctor may also recommend other therapies to help lower ammonia levels.

Always consult your doctor with questions about your prescribed dose. Your doctor may discuss with you the need to be on a restricted diet while you take Carbaglu.

Follow the instructions provided and use Carbaglu until your doctor tells you to stop.

When to take Carbaglu

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

How to take Carbaglu

- Carbaglu tablets should not be swallowed whole or crushed.

Adults

- Each 200mg 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 200mg 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 the same way as above, with the tube flushed with water after administration.

If you forget to use Carbaglu

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose 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 use too much Carbaglu

If you think that you have used too much Carbaglu, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Carbaglu?

Things you should do

Your doctor may ask you to have your liver, kidney, heart functions and blood tests 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.

Tell your doctor if you have renal impairment. Your daily dose may need to be reduced.

Call your doctor straight away if you:

- 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 any doctor, dentist or pharmacist you visit that you are using Carbaglu.

Things you should 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 tells you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Carbaglu affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your tablets in the container until it is time to take them. If you take the tablet out of the bottle they may not keep well.
- Store the unopened bottle in a refrigerator at 2°C to 8°C. Do not freeze the tablets.
- Once the tablet bottle has been opened, the opened bottle can be stored in a cool dry place away from moisture, heat or sunlight; for example, do not store:
 - in the bathroom or near a sink, or
 - in the car or on windowsills.

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.

Keep your tablets where young children cannot reach them.

When to discard your medicine

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal disorders: <ul style="list-style-type: none">• Diarrhoea• Vomiting• Abdominal pain General disorders: <ul style="list-style-type: none">• Fever or high temperature• Increased sweating Cardiac disorders: <ul style="list-style-type: none">• Slowed heartbeat (bradycardia)	Speak to your doctor if you have any of these less serious side effects and they worry you.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Carbaglu contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">• Carglumic acid
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Microcrystalline cellulose• Sodium lauryl sulphate• Hypromellose• Croscarmellose sodium• Silica colloidal anhydrous• Sodium stearyl fumarate

This medicine does not contain lactose or gluten.

Do not take this medicine if you are allergic to any of these ingredients.

What Carbaglu looks like

Carbaglu dispersible tablets are a white bar-shaped tablet, with 4 punches on one side and with 3 break-mark on both sides. The tablets are elongated and can be divided into equal halves.

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 bottle (Aust R 215632).

Who distributes Carbaglu

Recordati Rare Diseases Australia Pty Ltd

Level 10

100 Arthur Street

North Sydney

NSW 2060

Australia

Phone: +61 (0) 408 061 403

rrdaustriainfo@recordati.com

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