

New Zealand Consumer Medicine Information

Carglumic Acid (Sovereign Medical)

Carglumic Acid 200 mg Dispersible Tablets

What is in this leaflet

Please read this leaflet carefully before you start using Carglumic Acid.

This leaflet answers some common questions about Carglumic Acid. It does not contain all 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 using Carglumic Acid against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Carglumic Acid is used for

Your medicine is called Carglumic Acid (Sovereign Medical) 200 mg Dispersible Tablets. In this leaflet it will be called Carglumic Acid.

Carglumic Acid can help to eliminate high ammonia levels in the blood. Ammonia is especially toxic for the brain and can lead, in severe cases, to reduced levels of consciousness and to coma.

High levels of ammonia in the blood may be due to:

- the lack of a specific liver enzyme (N-acetylglutamate synthase). Patients with this rare disorder are not able to eliminate nitrogen waste, which builds up after eating protein. This disorder persists throughout the life of the affected patient, requiring lifelong treatment.
- isovaleric acidaemia, methylmalonic acidaemia or propionic acidaemia. Patients suffering from one of these disorders need treatment during the hyperammonaemia crisis.

Your doctor may have prescribed Carglumic Acid for another reason.

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

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

Before you use Carglumic Acid

When you must not use it

Do not use Carglumic Acid if:

- if you are hypersensitive (allergic) to carglumic acid or any of the other ingredients of these tablets (see the Product Description section of this document);
- during breast-feeding.

If you are not sure whether you should start using Carglumic Acid, talk to your doctor.

Before you start to use it

Carglumic Acid treatment should be initiated under the supervision of a doctor experienced in treating metabolic disorders.

Your doctor will evaluate your individual response to carglumic acid before starting any long-term treatment. The dose should be individually adjusted in order to maintain normal ammonia plasma levels.

Your doctor may prescribe a supplement called arginine, or restrict your protein intake.

In order to follow up your condition and your treatment, your doctor may examine your liver, kidneys, heart and blood on a regular basis.

Carglumic Acid contains sodium

This medicinal product contains up to 3 mg of sodium per tablet.

The maximum recommended daily dose of this medicinal product contains 396 mg sodium (found in table salt). This is equivalent to 20% of the adult recommended maximum daily dietary intake for sodium.

Talk to your doctor or pharmacist if you need 132 or more tablets daily for a prolonged period of time, especially if you have been advised to follow a low salt (sodium) diet.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Carglumic Acid.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Carglumic Acid.

How to use Carglumic Acid

How much to take

Always take Carglumic Acid exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

The usual dose:

The initial daily dose is usually 100 mg per kilogram of body weight, up to a maximum of 250 mg per kilogram of body weight (for example, if you weight 10kg, you should take 1g per day, or 5 tablets).

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

Your doctor will determine the dose suitable to you in order to maintain normal ammonia levels in your blood.

When to take it

Take carglumic acid before meals or feeds.

Disperse the tablets in at least 5 to 10 ml of water and take it immediately. The suspension will have a slightly acidic taste.

Carglumic Acid should ONLY be given by mouth, or through a feeding tube into the stomach (using a syringe, if necessary).

When the patient is in hyperammonaemic coma, Carglumic Acid is administered by fast push through a syringe via the tube set up to feed them.

How long to take it

Do not stop taking Carglumic Acid without informing your doctor.

If you forget to take it

If you forget to take a dose take the next dose at the usual time. DO NOT take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

While you are using Carglumic Acid

Things you must do

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

The effects of Carglumic Acid on pregnancy and the unborn child are not known. Please consult your doctor for advice if you are pregnant or planning to become pregnant.

Do not breast feed your baby if you are taking Carglumic acid. The excretion of carglumic acid into breast milk has not been studied in women. Nevertheless, carglumic acid has been shown to be present in the milk of lactating rats with potential toxic effects for their fed pups.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Carglumic Acid.

Things you must not do

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

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest

hospital, if you think that you or anyone else may have taken too much Carglumic Acid.

Do this even if there are no signs of discomfort or poisoning.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Carglumic Acid.

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

The following side effects were reported as follows:

- *Common (may affect up to 1 in 10 people)*: increased sweating
- *Uncommon (may affect up to 1 in 100 people)*: reduced heartbeat, diarrhoea, fever, vomiting increased transaminases (enzymes that may indicate liver damage).
- *Not known*: rash

If any of these side effects becomes serious please tell your doctor or pharmacist.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using Carglumic Acid

Storage

Keep this medicine out of the sight and reach of children.

Do not use after the expiry date stated on the tablet container.

Store at or below 25°C.

After first opening of the tablet container: do not refrigerate, do not freeze. Discard 1 month after first opening.

Keep the container tightly closed in order to protect from moisture.

Disposal

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

What it looks like

Carglumic Acid 200 mg Dispersible Tablets are white to off-white elongated tablets with three score marks on each side and embossed with 'N's on one side.

Carglumic Acid is presented in container of 5, 15 and 60 tablets.
Not all pack sizes may be marketed.

Ingredients

Active ingredient(s):

The active substance is carglumic acid. Each tablet contains 200 mg of carglumic acid.

Inactive ingredients:

The other ingredients are microcrystalline cellulose, croscarmellose sodium, sodium laurilsulfate, colloidal anhydrous silica, sodium stearyl fumarate.

Sponsor Details

Carglumic Acid is supplied in New Zealand by:

Te Arai BioFarma Ltd

PO Box 46205
Herne Bay
Auckland

NEW ZEALAND

0800 832 724

Date of Preparation

This leaflet was prepared on 20 October 2023.