

Package leaflet: Information for the user
Carbaglu 200 mg dispersible tablets
carglumic acid

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Carbaglu is and what it is used for
2. What you need to know before you take Carbaglu
3. How to take Carbaglu
4. Possible side effects
5. How to store Carbaglu
6. Contents of the pack and other information

1. What Carbaglu is and what it is used for

Carbaglu can help eliminating excessive ammonia plasma levels (elevated ammonia level in the blood). Ammonia is especially toxic for the brain and leads, in severe cases, to reduced levels of consciousness and to coma.

Hyperammonaemia 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 during the entire life of the affected patient and therefore the need for this treatment is lifelong.
- isovaleric acidemia, methylmalonic acidemia or propionic acidemia. Patients suffering from one of these disorders need treatment during the hyperammonaemia crisis.

2. What you need to know before you take Carbaglu

Do not take Carbaglu

If you are allergic to carglumic acid or any of the other ingredients of this medicine (listed in section 6).

Do not take Carbaglu during breast-feeding

Warnings and precautions

Talk to your doctor or pharmacist before taking Carbaglu.

Carbaglu treatment should be initiated under the supervision of a physician experienced in the treatment of metabolic disorders.

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

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

Your doctor may prescribe supplemental arginine or restrict your protein intake.

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

Other medicines and Carbaglu

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Carbaglu with food and drink

Carbaglu must be taken orally before meals or feedings.

The tablets must be dispersed in a minimum of 5 to 10 ml of water and taken immediately. The suspension has a slightly acidic taste.

Pregnancy and breast-feeding

The effects of Carbaglu on pregnancy and the unborn child are not known.

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

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

Driving and using machines

Effects on the ability to drive and use machines are not known.

3. How to take Carbaglu

Always take this medicine exactly as your doctor has told you. 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.

Carbaglu should ONLY be administered by mouth or via a feeding tube into the stomach (using a syringe, if necessary).

When the patient is in hyperammonaemic coma, Carbaglu is administered by fast push through a syringe via the tube set up and used to feed you.

Tell your doctor in case you are suffering from renal impairment. Your daily dose should be reduced.

If you take more Carbaglu than you should

Ask your doctor or pharmacist for advice.

If you forget to take Carbaglu

Do not take a double dose to make up for forgotten doses.

If you stop taking Carbaglu

Do not stop Carbaglu without informing your doctor.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects were reported as follows: very common (may affect more than 1 in 10 people), common (may affect up to 1 in 10 people), uncommon (may affect up to 1 in 100 people), rare (may affect up to 1 in 1,000 people), very rare (may affect up to 1 in 10,000 people) and not known (frequency cannot be estimated from the available data).

- *Common*: increased sweating
- *Uncommon*: bradycardia (decreased frequency of the heart), diarrhoea, fever, increased transaminases, vomiting
- *Not known*: rash

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system **Yellow Card Scheme** Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store carbaglu

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

Do not use this medicine after the expiry date which is stated on the tablet container after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).

After first opening of the container: do not refrigerate, do not store above 30°C.

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

Write the date of opening on the tablet container. Discard 3 months after first opening.

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

6. Contents of the pack and other information

What Carbaglu contains

- The active substance is carglumic acid. Each tablet contains 200 mg of carglumic acid.
- The other ingredients are microcrystalline cellulose, sodium laurilsulfate, hypromellose, croscarmellose sodium, silica colloidal anhydrous, sodium stearyl fumarate.

What Carbaglu looks like and contents of the pack

Carbaglu 200mg tablet is a bar-shaped tablet, with 4 punches on one side with 3 break-mark sides. Carbaglu is presented in a plastic container of 5, 15 and 60 tablets which is closed with a child resistant cap.

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