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.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

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 acidaemia, methylmalonic acidaemia or propionic acidaemia. Patients suffering from one of these disorders need treatment during the hyperammonaemia crisis.

2. BEFORE YOU TAKE CARBAGLU

Do not take Carbaglu:
Do not take Carbaglu if you are hypersensitive (allergic) to carglumic acid or any of the other ingredients of Carbaglu.
Do not take Carbaglu during breast-feeding

Take special care with 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.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking 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. Please consult your doctor for advice if you are pregnant or planning to become pregnant.
The excretion of carglumic acid into breast milk has not been studied in women. Nevertheless, as carglumic 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 Carbaglu exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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.

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 individual 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, Carbaglu can have side effects, although not everybody gets them.

The following side effects were reported as follows: very common (occurring in at least one in 10 patients), common (occurring in at least one in 100 patients), uncommon (occurring in at least one in1,000 patients), rare (occurring in at least one in 10,000 patients), very rare (occurring in at least one in 100,000 patients) 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CARBAGLU

Keep out of the reach and sight of children.

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

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.

6. FURTHER 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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For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu. There are also links to other websites about rare diseases and treatments.