

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations)
1986

This medicine is dispensed with a doctor's prescription only

CARBAGLU Dispersible Tablets

Each tablet contains:

carglumic acid 200 mg

Inactive ingredients see section 6 ("Additional information") in this leaflet.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine used for?

CARBAGLU can help eliminate excess ammonia from the blood. When ammonia accumulates in your blood it is toxic mainly to the brain. In severe cases, its accumulation may cause decreased level of consciousness and coma.

CARBAGLU is used to treat hyperammonemia (a condition in which high levels of ammonia are found in the plasma), in patients with hyperammonemia caused by:

- lack of a liver enzyme called N-acetylglutamate synthase. Patients with this rare condition cannot eliminate nitrogen, a waste material which accumulates in their body as a result of eating protein. This medical condition persists throughout a patient's life, therefore the need for this treatment is lifelong.
- certain acidemia conditions (propionic acidemia, isovaleric acidemia, methylmalonic acidemia). Patients suffering from one of these conditions must be treated during the hyperammonemia stage of their illness.

Therapeutic group:

CPS (carbamoyl phosphate synthase) activator.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient carglumic acid or to any of the other ingredients in this medicine.
- You are breastfeeding

Special warnings about using this medicine

- Your doctor will evaluate your individual response to carglumic acid before deciding on long-term treatment.
- CARBAGLU dosage should be adjusted in order to achieve normal ammonia blood levels.
- Your doctor may prescribe the dietary supplement arginine or restrict your daily protein intake.
- During treatment with this medicine liver function tests, kidneys, heart and blood tests should be performed.

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Taking CARBAGLU and food

Take this medicine before meals.

Disperse the tablet in 5-10 ml of water and drink immediately. The suspension that is formed has a slightly sour taste.

Pregnancy and breastfeeding:

The effect of this medicine on pregnancy and the fetus is unknown.

Consult your doctor if you are pregnant or planning to become pregnant.

The excretion of carglumic acid into breast milk has not been studied in women. But, as this medicine has been detected in the milk of lactating rats it is possibly toxic for the offspring. Do not use this medicine if you are breastfeeding.

Driving and using machines:

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

3. How to use this medicine?

Always use this medicine according your doctor`s instructions.

Check with your doctor or pharmacist if you are not sure.

The usual dose: the initial 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 weigh 10 kg you must take 1 gram per day, meaning 5 tablets). For patients suffering from lack of N-acetylglutamate synthase, in the long term, the daily dose usually ranges from 10 to 100 mg per kilogram body weight.

Your doctor will determine the right dose for you.

- Take CARBAGLU by mouth only, or through a feeding tube (use a syringe if necessary).
- When the patient is in coma, Carbaglu is given through the feeding tube set up.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take this medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your doctor.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor or pharmacist.

If you stop taking this medicine its beneficial effect will stop.

Irregular treatment may not result in the desired effect.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using CARBAGLU may cause side effects in some patients. Do not be alarmed by the list of side effects; you may not experience any of them.

Common side effects (affect 1-10 in 100 users):

excessive sweating.

Uncommon side effects (affect 1-10 in 1,000 users):

bradycardia (slow heart rate), diarrhea, fever, increased transaminases (liver enzymes), vomiting.

Side effects of unknown frequency:

rash.

If any side effect gets worse or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il/>.

5. How to store this medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.
- Do not use this medicine after the expiry date (exp. date) which is stated on the package/ bottle/ carton/ label. The expiry date refers to the last day of that month.
- **Storage conditions:**
keep refrigerated (2°C-8°C), this is the temperature range in most household refrigerators.
Store in the original package.
- Do not store in the refrigerator after first opening the container, do not store above 30°C.
- Keep the container tightly closed to protect from moisture.
- Write the opening date on the container.
- Use within three months of first opening.

4. ADDITIONAL INFORMATION

- In addition to the active ingredient this medicine also contains – microcrystalline cellulose, sodium laurilsulfate, hypromellose, croscarmellose sodium, silica colloidal anhydrous, sodium stearyl fumarate.
- What CARBAGLU looks like and contents of the pack –
A bar-shaped tablet with the letter C embossed 4 times on one side, and 3 score lines on each side of the tablet.

CARBAGLU is supplied in a plastic container of 5 tablets, 15 tablets or 60 tablets, with a child-resistant cap.

Not all pack sizes may be marketed.

- Name of manufacturer and address: Recordati Rare Disease, Puteaux, France
- Name of registration holder and address: Medison Pharma LTD, 10 Hashiloach st. P.O. Box 7090, Petach Tikva.

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Registration number of the medicine in the Ministry of Health's National Drug Registry: 147-76-33555

