PATIENT INFORMATION LEAFLET

APPROVED
Responsible Pharmacist
Sign: Jamaré Date: 30 June 2020

SCHEDULING STATUS: S4

CARBAGLU 200 mg (dispersible tablet)

Carglumic acid

Sugar free

Read all of this leaflet carefully before you start taking CARBAGLU

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other healthcare provider.
- CARBAGLU has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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 eliminate excessive ammonia plasma levels (this is elevated ammonia levels 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. What you need to know before you take CARBAGLU

Do not take CARBAGLU:

- if you are hypersensitive (allergic) to carglumic acid or any of the other ingredients of CARBAGLU.
- if you are breastfeeding your baby.

Warnings and precautions

CARBAGLU treatment should be initiated under the supervision of a doctor experienced in the treatment of metabolic disorders.

Your doctor will initiate and monitor your therapy.

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

Other medicines and CARBAGLU

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

CARBAGLU with food and drink

CARBAGLU must be taken orally before meals or feedings.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking CARBAGLU.

Pregnancy

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

Breastfeeding

As carglumic acid has been shown to be present in the milk of lactating rats, you should not breastfeed your baby if you are taking CARBAGLU.

Fertility

The effects of CARBAGLU on fertility are not known.

Driving and using machines

It is not always possible to predict to what extent CARBAGLU may interfere with your daily activities. You should ensure that you do not engage in the driving of a vehicle or use machines until you are aware of the measure to which CARBAGLU affects you.

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

3. How to take CARBAGLU

Do not share medicines prescribed for you with any other person.

Always take CARBAGLU exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are not sure.

The usual initial daily dose is 100 mg per kilogram of body weight, up to a maximum of 250 mg per kilogram of body weight.

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) before meals or feedings.

CARBAGLU dosages can be divided into two to four doses.

The tablets must be dispersed in a minimum of 5 - 10 ml of water and ingested immediately.

The suspension has a slightly acidic taste.

Your doctor will tell you how long your treatment with CARBAGLU will last. Do not stop treatment early. If you have the impression that the effect of CARBAGLU is too strong or too weak, tell your doctor or pharmacist.

If you take more CARBAGLU than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take CARBAGLU

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

4. Possible side effects

CARBAGLU can have side effects.

Not all side effects reported for CARBAGLU are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CARBAGLU, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking CARBAGLU and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting (dizziness).

These are all very serious side effects. If you have them, you may have had a serious reaction to CARBAGLU. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent:

a) Undesirable effects in N-acetylglutamate synthase deficiency

- Increased sweating

Less frequent:

a) Undesirable effects in N-acetylglutamate synthase deficiency

- Increased liver enzymes (increased transaminases)

b) Undesirable effects in organic acidaemia

- Slow heartbeat (bradycardia)
- Diarrhoea
- Vomiting
- Fever

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of CARBAGLU.

5. How to store CARBAGLU

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at 2 °C to 8 °C (Refrigerate. Do not freeze). Protect from light.

After first opening of the tablet container:

Do not refrigerate.

Store at or below 30 °C for not longer than three months.

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

KEEP OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the label / carton / bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CARBAGLU contains

The active substance is carglumic acid.

The other ingredients are croscarmellose sodium, hypromellose, microcrystalline cellulose, silica colloidal anhydrous, sodium laurylsulfate and sodium stearyl fumarate.

What CARBAGLU looks like and contents of the pack

CARBAGLU is a white, dispersible, bar-shaped tablet, scored on both sides and engraved on one side (4 punches with the letter c), size 18,0 x 6,0 mm.

The tablet can be divided into equal halves.

Container:

A 30 ml white round high density polyethylene container suitable for 5 and 15 tablets, with a white round 35 mm polypropylene child-resistant tamper-evident screw cap with a mounted desiccant (silica gel).

A 75 ml white round high density polyethylene container suitable for 60 tablets, with a white round 45 mm polypropylene child-resistant tamper-evident screw cap with integrated desiccant (silica gel).

Holder of Certificate of Registration

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