

Carglumic Acid Waymade 200 mg Dispersible tablets

Active ingredient

Each tablet contains 200 mg carglumic acid.

Inactive ingredients and allergens in this medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

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 intended for?

Carglumic Acid Waymade 200 mg is used to treat hyperammonaemia (high levels of ammonia in the plasma) due to:

- the lack of a liver enzyme called N-acetylglutamate synthase. Patients with this rare disease are not able to eliminate nitrogen, a waste substance that builds up in their body after eating protein. This medical condition persists throughout the life of the affected patient, and therefore requires lifelong treatment.
- certain acidosis conditions (propionic acidaemia, isovaleric acidaemia, methylmalonic acidaemia); patients with any of these disorders must be treated during the hyperammonaemia stages of their disease.

Therapeutic group: CPS (carbamoyl phosphate synthase) activator

Carglumic Acid Waymade 200 mg can help to eliminate excess ammonia from the blood. When ammonia builds up in the blood it is especially toxic for the brain. In severe cases, build-up can lead to reduced consciousness and to coma.

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 (see section 6)
- you are breast-feeding

Special warnings about using this medicine

- Your doctor will evaluate your individual response to carglumic acid before deciding on long term treatment.
- Your dose of Carglumic Acid Waymade 200 mg should be individually adjusted for you to achieve normal blood levels of ammonia.
- Your doctor may prescribe a dietary supplement called arginine, or restrict your daily protein intake.

Tests and follow-up

During the course of treatment with this medicine, you must have regular check-ups of your liver, kidneys, and heart function and blood tests.

Interactions with other medicines

If you are taking or have recently taken other medicines, including non-prescription

medications and dietary supplements, tell your doctor or pharmacist.

Using this medicine and food

Take the medicine before meals.

Disperse the tablet in at least 5–10 ml of water and drink immediately. The suspension will have a slightly acidic taste.

Pregnancy and breast-feeding

Pregnancy

The effect of this medicine on your pregnancy and unborn child is not known.

Please consult your doctor if you are pregnant or planning to become pregnant.

Breast-feeding

Do not use this medicine if you are breast-feeding. 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.

Driving and using machines

There are no known effects of Carglumic Acid Waymade 200 mg on the ability to drive and use machines.

Important information about some of this medicine's ingredients

This medicine contains up to 3 mg of sodium per tablet. The maximum recommended daily dose of this medicine contains 396 mg sodium (an ingredient of table salt). This amount is equivalent to 20% of the adult recommended maximum daily 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.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

The recommended dosage is usually:

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 weigh 10 kg, you should take 1 g per day, that is 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 that is right for you.

- Carglumic Acid Waymade 200 mg should only be given by mouth, or through a feeding tube into the stomach (using a syringe, if necessary).
- When the patient is in a coma, Carglumic Acid Waymade 200 mg is administered via the tube set up to feed them.

Do not exceed the recommended dose.

The tablet can be divided into equal halves.

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 the 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 be lost.

If you take this treatment intermittently you may not get the desired effect.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

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

4. Side effects

Like with all medicines, using Carglumic Acid Waymade 200 mg may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Common side effects (may affect 1–10 in 100 users)
increased sweating

Uncommon side effects (may affect 1–10 in 1,000 users)
bradycardia (slow heartbeat), diarrhoea, fever, increased transaminases (liver enzymes), vomiting.

Side effects of unknown frequency (the frequency of these effects has not been established yet)
rash

If you experience any side effect, 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 the 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 a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package/blister/label. The expiry date refers to the last day of that month.

Storage conditions:

Store below 25°C. Do not refrigerate, do not freeze.

Bottle pack: Keep the bottle tightly closed in order to protect from moisture.

6. Additional information

In addition to the active ingredient, this medicine also contains:
microcrystalline cellulose, croscarmellose sodium, sodium stearyl fumarate, colloidal anhydrous silica, sodium laurilsulfate.

What the medicine looks like and contents of the pack:

white to off-white elongated tablet, embossed with 'N' on one side and with score marks on both sides.

Carglumic Acid Waymade 200 mg is supplied in a plastic bottle and in blister packs of 5, 15, and 60 tablets. The bottle has a child-resistant cap and contains a desiccant.

Not all pack sizes/types may be marketed.

Manufacturer's name and address:

Waymade Plc, Sovereign House, Miles Gray Road, Basildon, Essex SS14 3FR, UK.

Registration holder's name and address: MBI Pharma Ltd., POB 5061, Kadima.

Revised in July 2023 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 173-40-36429-00