Package leaflet: Information for the user

Kargluminsyra Waymade 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 your 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 (Invented name) is and what it is used for

Your medicine is called (Invented name) 200 mg Dispersible Tablets. In this leaflet it will be called (Invented name).

(Invented name) can help to eliminate high ammonia levels in the blood. Ammonia is especially toxic for the brain and can lead, in severe cases, to reduced levels of consciousness and to coma.

High levels of ammonia in the blood 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 throughout the life of the affected patient, requiring lifelong treatment.
- 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 (Invented name)

Do not take (Invented name):
- if you are hypersensitive (allergic) to (Invented name) or any of the other ingredients of these tablets (see section 6 for a list of ingredients);
- during breast-feeding.

Warnings and precautions
(Invented name) treatment should be initiated under the supervision of a doctor experienced in treating metabolic disorders.
Your doctor will evaluate your individual response to carglumic acid before starting any long term treatment. The dose should be individually adjusted in order to maintain normal ammonia plasma levels.

Your doctor may prescribe a supplement called arginine, or restrict your protein intake.

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

Other medicines and (Invented name)
Please tell your doctor or pharmacist if you are taking, have recently taken or might take, any other medicines.

(Invented name) with food and drink
Take (Invented name) before meals or feeds.
Disperse the tablets in at least 5 to 10 ml of water and take it immediately. The suspension will have a slightly acidic taste.

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

Pregnancy
The effects of carglumic acid on pregnancy and the unborn child are not known. Please consult your doctor for advice if you are pregnant or planning to become pregnant.

Breast-feeding
Do not breast-feed your baby if you are taking (Invented name). 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
Effects on the ability to drive and use machines are not known.

(Invented name) contains sodium
This medicinal product contains up to 3 mg of sodium per tablet.

The maximum recommended daily dose of this medicinal product contains 396 mg sodium (found in table salt). This is equivalent to 20% of the adult recommended maximum daily dietary 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 take (Invented name)

Always take (Invented name) exactly as your doctor has instructed you. You should 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 weigh 10 kg, you should take 1 g 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.

(Invented name) should ONLY be given by mouth, or through a feeding tube into the stomach (using a syringe, if necessary).

When the patient is in hyperammonaemic coma, (Invented name) is administered by fast push through a syringe via the tube set up to feed them.

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

If you take more (Invented name) than you should:
If you accidentally take too much of your medicine, tell your doctor at once or contact your nearest hospital casualty department immediately. Take your medicine and this leaflet with you.

If you forget to take (Invented name)
If you forget to take a dose take the next dose at the usual time. DO NOT take a double dose to make up for a forgotten dose.

If you stop taking (Invented name)
Do not stop taking (Invented name) 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, (Invented name) can have side effects, although not everybody gets them.

The following side effects were reported as follows:
• *Common (may affect up to 1 in 10 people):* increased sweating.
• *Uncommon (may affect up to 1 in 100 people):*
reduced heart beat, diarrhoea, fever, vomiting, increased transaminases (enzymes that may indicate liver damage).
• *Frequency not known:* rash.

If any of these side effects becomes 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store (Invented name)

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, carton or blister after EXP. The expiry date refers to the last day of that month.

Bottle
This medicinal product does not require any special storage conditions.

After first opening of the tablet container: do not refrigerate, do not freeze. Discard 1 month after first opening.

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

Blister
This medicinal product does not require any special storage conditions.

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

What (Invented name) looks like and contents of the pack
(Invented name) 200 mg Dispersible Tablets are white to off-white elongated dispersible tablets, 18 mm x 6 mm, with three score marks on both side and engraved with 'N's on one side.
The tablet can be divided into equal doses.
(Invented name) is presented in containers or blisters of 5, 15 and 60 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer
Drehm Pharma GmbH, Grünbergstraße 15/3/3, 1120 Wien, Austria
or
Wayamde B.V., Herikerbergweg 88, 1101 CM, Amsterdam, Netherlands

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