Package leaflet: Information for the user

Ucedane 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 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 Ucedane is and what it is used for

Ucedane 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. What you need to know before you take Ucedane

Do not take Ucedane:
- if you are allergic to carglumic acid or any of the other ingredients of Ucedane (listed in section 6);
- Do not take Ucedane during breast-feeding.

Warnings and precautions
Talk to your doctor or pharmacist before taking Ucedane.

Ucedane 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.

Other medicines and Ucedane
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Ucedane with food and drink
Ucedane 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.

Pregnancy and Breast-feeding
The effects of Ucedane on pregnancy and the unborn child are not known.
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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 Ucedane.

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

Ucedane contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per maximum daily dose that is to say essentially 'sodium-free'

3. How to take Ucedane

Always take this medicine exactly as your doctor has told you. 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 weight 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.

Ucedane 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, Ucedane is administered by fast push through a syringe via the tube set up and used to feed you.

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

If you take more Ucedane than you should
Ask your doctor or pharmacist for advice.

If you forget to take Ucedane

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

If you stop taking Ucedane
Do not stop Ucedane without informing your doctor.

If you have any further questions on the use of this medicine, ask your doctor, or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects were reported as follows: very common (may affect more than 1 in 10 people), common (may affect up to 1 in 10 people), uncommon (may affect up to 1 in 100 people), rare (may affect up to 1 in 1,000 people), very rare (may affect up to 1 in 10,000 people) 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 or, pharmacist. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ucedane

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

This medicine 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 Ucedane contains
- The active substance is carglumic acid. Each tablet contains 200 mg of carglumic acid.
- The other ingredients are microcrystalline cellulose, colloidal anhydrous silica, sodium stearyl fumarate (see section 2 “Ucedane contains sodium”), mannitol, copovidone K28, crospovidone type B.

What Ucedane looks like and contents of the pack
Ucedane dispersible tablets are rod-shaped, white, and biconvex with three score lines on both sides and engraving “L/L/L/L” on one side.
Approximate tablet dimensions are 17 mm in length and 6 mm in width.
The tablet can be divided into four equal doses.
The tablets are presented in aluminium/aluminium blister packed in cartons.
Pack size of 12 or 60 dispersible tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
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1244 RL Ankeveen
The Netherlands

Manufacturer
Eurocept International BV
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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