UCEDANE 200 mg dispersible tablet

For oral use.

Prescription-only medicine	ATC: A16AA05	Active substance: Carglumic acid

INGREDIENTS

Active substance: Carglumic acid

Excipient(s): Contains microcrystalline cellulose, mannitol, colloidal anhydrous silica, sodium stearyl fumarate, crospovidone type B and copovidone K 28.

Packaging: Available in packs containing 12 or 60 tablets in aluminium blisters, placed in a cardboard box.

Read this PACKAGE LEAFLET carefully before you start using this medicine, because it contains important information for you.

- Keep this leaflet. You may need to read it again later.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you personally, do not pass it on to others.
- When you go to a doctor or hospital during the use of this medicine, tell your doctor that you are using this medicine.
- Follow the instructions in this leaflet exactly. Do not use **high or low** doses other than the recommended dose of the medicine.

IN THIS PACKAGE LEAFLET:

What is UCEDANE and what is it used for?

UCEDANE is available as rod-shaped, white, biconvex and breakable (with 3 notches on both sides) dispersible tablets with "L/L/L/L" embossed on one side. The approximate tablet dimensions are 11 mm in length and 6 mm in width. The tablet can be divided into four equal doses. It is supplied in packs containing 12 or 60 tablets in aluminium blisters, placed in a cardboard box.

UCEDANE can help to reduce high ammonia levels in the blood. Ammonia is toxic, especially to the brain, and in severe cases can lead to reduced consciousness and coma.

INDICATION 1

N-acetylglutamate synthase deficiency

A deficiency of N-acetylglutamate synthase, a special enzyme found in the liver. Patients with this rare disease cannot excrete nitrogen waste products that accumulate after protein intake. This condition is lifelong in affected patients and therefore requires lifelong treatment.

INDICATION 2

Organic Acidemias

Isovaleric acidemia, methylmalonic acidemia or propionic acidemia. Patients with any of these disorders need treatment during a hyperammonemia crisis.

Before you use UCEDANE

Do NOT use UCEDANE in the following situations

If you are allergic to carglumic acid or any of the excipients in UCEDANE.

If you are pregnant.

If you are breastfeeding.

Use UCEDANE CAREFULLY in the following situations

Consult your doctor and pharmacist before taking UCEDANE.

UCEDANE treatment should be initiated under the supervision of a physician experienced in the treatment of metabolic disorders.

Before starting any long-term treatment, your doctor will test your individual response to carglumic acid.

The dose should be adjusted individually to maintain normal ammonia plasma levels.

Your doctor may give you arginine supplements or limit your protein intake.

To monitor your condition and treatment, your doctor may regularly check your liver, kidneys, heart and blood.

Tell your doctor if you have kidney failure. Your daily dose needs to be reduced depending on the degree of your kidney failure.

If these warnings apply to you at any time in the past, please consult your doctor.

Using UCEDANE with food and drink

UCEDANE should be taken orally before meals or feeding.

Tablets should be dissolved in at least 5 to 10 mL of water and drunk immediately.

Pregnancy

Consult your doctor or pharmacist before using the medicine.

The effects of UCEDANE on pregnancy and the unborn child (fetus) are unknown. Consult your doctor or pharmacist

if you are pregnant or planning to become pregnant.

UCEDANE should not be used during pregnancy.

If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breastfeeding

Consult your doctor or pharmacist before using the medicine.

If you are breastfeeding, consult your doctor or pharmacist before taking this medicine.

It has not been studied whether carglumic acid passes into breast milk in women. However, since carglumic acid has been shown to be present in the milk of lactating rats and to have potential toxic effects on suckling offspring, you should not breastfeed your baby while taking UCEDANE.

Driving and using machines

Its effect on driving and using machines is unknown.

Important information about some of the excipients in UCEDANE

Ucedane contains sodium. This medicine contains less than 1 mmol (23 mg) of sodium per maximum daily dose, i.e., it is essentially "sodium-free".

Using with other medicines

If you are currently using or have recently used any prescription or non-prescription medicine, please inform your doctor or pharmacist about them.

How to use UCEDANE?

Instructions for proper use and dose/frequency of administration:

Always follow your doctor's instructions exactly when using UCEDANE. If you are not sure, consult your doctor or pharmacist.

General dose:
The initial daily dose applied is usually 100 mg per kilogram of body weight, and doses up to a maximum of 250 mg per kilogram of body weight can be used (for example, if you weigh 10 kg, you should take 1 g or 5 tablets per day). In patients with N-acetylglutamate synthase deficiency, in the long term, the daily dose generally varies between 10 mg and 100 mg per kilogram of body weight.

Your doctor will determine the appropriate dose to keep your blood ammonia levels normal.

Route and method of administration:

Tablets should be dispersed in at least 5-10 mL of water and drunk immediately. UCEDANE should ONLY be administered orally or into the stomach via a feeding tube.

If the patient is in a hyperammonemic coma (excessive elevation of ammonia levels in the blood), UCEDANE is quickly administered by syringe into the tube placed for feeding.

Tell your doctor if you have kidney failure. Your daily dose needs to be reduced depending on the degree of your kidney

failure.

Different age groups:

Use in children:
'Your doctor will determine and administer the dose of your medicine depending on your disease.'

Use in the elderly:
'Your doctor will determine and administer the dose of your medicine depending on your disease.'

Special use situations:

Kidney/liver failure:
Your doctor will adjust your daily dose according to the degree of your kidney failure as indicated below:

Dose adjustment should be made according to GFR (Glomerular filtration rate).

Patients with moderate renal impairment (GFR 30-59 mL/minute)

The recommended initial dose for patients with hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency or organic acidemia is 50 mg/kg/day to 125 mg/kg/day.

For long-term use, the daily dose should be in the range of 5 mg/kg/day to 50 mg/kg/day and should be individually adjusted to maintain normal ammonia plasma levels.

Patients with severe renal impairment (GFR ≤ 29 mL/minute)

The recommended initial dose for patients with hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency or organic acidemia is 15 mg/kg/day to 40 mg/kg/day.

For long-term use, the daily dose should be in the range of 2 mg/kg/day to 20 mg/kg/day and should be individually adjusted to maintain normal ammonia plasma levels.

If you used more UCEDANE than you should:

If you have used more UCEDANE than you should, talk to a doctor or pharmacist.

Undesirable effects such as tachycardia (increased heart rate), excessive sweating, increased bronchial secretions (respiratory tract secretions), increased body temperature and restlessness may be observed.

If you forget to use UCEDANE

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

Effects that may occur when treatment with UCEDANE is stopped

No effects are expected when treatment is stopped.

If you have the impression that the effect of UCEDANE is too strong or too weak, talk to your doctor or pharmacist.

What are the possible side effects?

Like all medicines, UCEDANE may cause side effects in people who are sensitive to the substances contained in it.

Side effects are listed as follows: Very common: May be seen in at least 1 in 10 patients. Common: May be seen in less than 1 in 10 patients but more than 1 in 100 patients. Uncommon: May be seen in less than 1 in 100 patients but more than 1 in 1,000 patients. Rare: May be seen in less than 1 in 1,000 patients. Very rare: May be seen in less than 1 in 10,000 patients. Unknown: Cannot be estimated from the available data.

Common:

Increased sweating

Uncommon:

Bradycardia (decreased heart rate)

Diarrhoea

Fever

Increased transaminases (liver enzymes)

Vomiting

Unknown:

Rash

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

Reporting 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 to the Turkish Pharmacovigilance Centre (TÜFAM) by clicking on the “Drug Side Effect Notification” icon on www.titck.gov.tr or by calling the side effect notification line 0 800 314 00 08. By reporting side effects, you can help provide more information on the safety of this medicine.

How to store UCEDANE?

Keep UCEDANE out of the sight and reach of children and in its packaging.

Store below 30°C at room temperature.

Use in accordance with the expiry date.

Do not use UCEDANE after the expiry date on the packaging.

The expiry date is the last day of the month specified (written after “exp” on the box or label).

Disposal of expired or unused medicines:

Do not throw away expired or unused medicines! Hand them over to the collection system determined by the Ministry of Environment, Urbanisation and Climate Change.

Marketing Authorisation Holder:

LUCANE PHARMA Sağlık Hizmetleri Ltd.Şti

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This package leaflet was approved on .....