

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
2. What you need to know before you take Ucedane
3. How to take Ucedane
4. Possible side effects
5. How to store Ucedane
6. Contents of the pack and other information

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.

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 this medicine (listed in section 6);
- 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. Consult your doctor for advice if you are pregnant or planning to become pregnant.

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 must 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.

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 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 of 200 mg). 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.

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 individual 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.

Common side effects (may affect up to 1 in 10 people):

- increased sweating

Uncommon side effects (may affect up to 1 in 100 people):

- bradycardia (decreased frequency of the heart),
- diarrhoea,
- fever,
- increased transaminases (liver enzymes),
- vomiting

Not known side effects (frequency cannot be estimated from the available data)

- rash

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. 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.
- The other ingredients are microcrystalline cellulose, colloidal anhydrous silica, sodium stearyl fumarate, 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.

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 tablets.

Marketing Authorisation Holder

Eurocept International BV
Trapgans 5
1244 RL Ankeveen
The Netherlands

Manufacturer

Lucane Pharma
172 rue de Charonne
75011 Paris
France

Eurocept International BV
Trapgans 5
1244 RL Ankeveen
The Netherlands

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

België/Belgique/Belgien

Lucane Pharma
Tél/Tel: + 33 153 868 750
info@lucanepharma.com

България

Lucane Pharma
Тел.: + 33 153 868 750
info@lucanepharma.com

Česká republika

Lucane Pharma
Tél/Tel: + 33 153 868 750
info@lucanepharma.com

Danmark

FrostPharma AB
Tlf: +45 808 20 101
info@frostpharma.com

Deutschland

Lucane Pharma
Tel: + 33 153 868 750
info@lucanepharma.com

Eesti

FrostPharma AB
Tel: +46 775 86 80 02
info@frostpharma.com

Ελλάδα

Lucane Pharma
Τηλ: + 33 153 868 750
info@lucanepharma.com

España

Lucane Pharma
Tel: + 33 153 868 750
info@lucanepharma.com

Lietuva

FrostPharma AB
Tel: +46 775 86 80 02
info@frostpharma.com

Luxembourg/Luxemburg

Lucane Pharma
Tél/Tel: + 33 153 868 750
info@lucanepharma.com

Magyarország

Lucane Pharma
Tel: + 33 153 868 750
info@lucanepharma.com

Malta

Lucane Pharma
Tel: + 33 153 868 750
info@lucanepharma.com

Nederland

Eurocept International BV
Tel: +31 35 528 39 57
info@eurocept.nl

Norge

FrostPharma AB
Tlf: +47 815 03 175
info@frostpharma.com

Österreich

Lucane Pharma
Tel: + 33 153 868 750
info@lucanepharma.com

Polska

Lucane Pharma
Tel: + 33 153 868 750
info@lucanepharma.com

France

Lucane Pharma
Tél: + 33 153 868 750
info@lucanepharma.com

Hrvatska

Lucane Pharma
Tel: + 33 153 868 750
info@lucanepharma.com

Ireland

Lucane Pharma
Tel: + 33 153 868 750
info@lucanepharma.com

Ísland

Lucane Pharma
Sími: + 33 153 868 750
info@lucanepharma.com

Italia

Lucane Pharma
Tel: + 33 153 868 750
info@lucanepharma.com

Κύπρος

Lucane Pharma
Τηλ: + 33 153 868 750
info@lucanepharma.com

Latvija

FrostPharma AB
Tel: +46 775 86 80 02
info@frostpharma.com

Portugal

Lucane Pharma
Tel: + 33 153 868 750
info@lucanepharma.com

România

Lucane Pharma
Tel: + 33 153 868 750
info@lucanepharma.com

Slovenija

Lucane Pharma
Tel: + 33 153 868 750
info@lucanepharma.com

Slovenská republika

Lucane Pharma
Tel: + 33 153 868 750
info@lucanepharma.com

Suomi/Finland

FrostPharma AB
Puh/Tel: +35 875 32 51 209
info@frostpharma.com

Sverige

FrostPharma AB
Tel: +46 775 86 80 02
info@medicalneed.com

United Kingdom

Lucane Pharma
Tel: + 33 153 868 750
info@lucanepharma.com

This leaflet was last revised in 09/2019

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.