ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Ucedane 200 mg dispersible tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dispersible tablet contains 200 mg of carglumic acid.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Dispersible tablet.
The 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.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Ucedane is indicated in treatment of

- hyperammonaemia due to N-acetylglutamate synthase primary deficiency.
- hyperammonaemia due to isovaleric acidaemia.
- hyperammonaemia due to methymalonic acidaemia.
- hyperammonaemia due to propionic acidaemia.

4.2 Posology and method of administration

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

Posology

- For N-acetylglutamate synthase deficiency:

Based on clinical experience, the treatment may be started as early as the first day of life. The initial daily dose should be 100 mg/kg, up to 250 mg/kg if necessary.
It should then be adjusted individually in order to maintain normal ammonia plasma levels (see section 4.4).
In the long term, it may not be necessary to increase the dose according to body weight as long as adequate metabolic control is achieved; daily doses range from 10 mg/kg to 100 mg/kg.

Carglumic acid responsiveness test
It is recommended to test individual responsiveness to carglumic acid before initiating any long term treatment. As examples:

- In a comatose child, starting dose is 100 to 250 mg/kg/day and measurement of ammonia plasma concentration at least before each administration is required. It should normalise within a few hours after starting Ucedane.
- In a patient with moderate hyperammonaemia, it is required to administer a test dose of 100 to 200 mg/kg/day for 3 days with a constant protein intake and perform repeated determinations of ammonia plasma concentration (before and 1 hour after a meal); and adjustment of the dose is necessary in order to maintain normal ammonia plasma levels.

- For isovaleric acidaemia, methylmalonic acidaemia and propionic acidaemia:

The treatment should start upon hyperammonaemia in organic acidaemia patients. The initial daily dose should be 100 mg/kg, up to 250 mg/kg if necessary.
It should then be individually adjusted in order to maintain normal ammonia plasma levels (see section 4.4).

Method of administration

This medicine is for oral use ONLY (ingestion or via nasogastric tube using a syringe, if necessary).

Based on pharmacokinetic data and clinical experience, it is recommended to divide the total daily dose into two to four intakes to be given before meals or feedings. The breaking of the tablets in halves allows most of the required posology adjustments. Occasionally, the use of quarter tablets may also be useful to adjust the posology prescribed by the physician.

The tablets must be dispersed in a minimum of 5-10 mL of water and ingested immediately or administered by fast push through a syringe via a nasogastric tube.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Breast-feeding during the use of carglumic acid is contraindicated (see sections 4.6 and 5.3).

4.4 Special warnings and precautions for use

Therapeutic monitoring

Plasma levels of ammonia and amino acids should be maintained within normal limits.
As very few data on the safety of carglumic acid are available, systematic surveillance of liver, renal, cardiac functions and haematological parameters is recommended.

Nutritional management

Protein restriction and arginine supplementation may be indicated in case of low protein tolerance.

Ucedane contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per maximum daily dose that is to say essentially ‘sodium-free’.

4.5 Interaction with other medicinal products and other forms of interaction

No specific interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy

For carglumic acid no clinical data on exposed pregnancies are available.
Animal studies have revealed minimal developmental toxicity (see section 5.3). Caution should be exercised when prescribing to pregnant women.

Breast-feeding

Although it is not known whether carglumic acid is secreted into human milk, it has been shown to be present in the milk of lactating rats (see section 5.3). Therefore, breast-feeding during the use of carglumic acid is contraindicated (see section 4.3).

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Reported adverse reactions are listed below, by system organ class and by frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/10) and uncommon (≥1/1,000 to <1/100) 100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000), not known (cannot be estimated from the available data).

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

- Table 1: Undesirable effects in N-acetylglutamate synthase deficiency

System Organ Class	**Frequency**		
	Common	**Uncommon**	**Not known**
Skin and subcutaneous tissue disorders	increased sweating		rash
Investigations		increased transaminases	

- Table 2 : Undesirable effects in organic acidaemia

System Organ Class	**Frequency**		
	Common	**Uncommon**	**Not known**
Cardiac disorders		bradycardia	
Gastrointestinal disorders		diarrhoea, vomiting	
Skin and subcutaneous tissue disorders			rash
General disorders and Administration site conditions		pyrexia	

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

In one patient treated with carglumic acid, where the dose was increased up to 750 mg/kg/day, symptoms of intoxication occurred which can be characterised as a sympathomimetic reaction:

tachycardia, profuse sweating, increased bronchial secretion, increased body temperature and restlessness. These symptoms resolved once the dose was reduced.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other alimentary tract and metabolism products - amino acids and derivatives; ATC code: A16AA05.

Mechanism of action

Carglumic acid is a structural analogue of N-acetylglutamate, which is the naturally occurring activator of carbamoyl phosphate synthetase, the first enzyme of the urea cycle.
Carglumic acid has been shown *in vitro* to activate liver carbamoyl phosphate synthetase. Despite a lower affinity of carbamoyl phosphate synthetase for carglumic acid than for N-acetylglutamate, carglumic acid has been shown *in vivo* to stimulate carbamoyl phosphate synthetase and to be much more effective than N-acetylglutamate in protecting against ammonia intoxication in rats. This could be explained by the following observations:
i) The mitochondrial membrane is more readily permeable for carglumic acid than for N-acetylglutamate
ii) Carglumic acid is more resistant than N-acetylglutamate to hydrolysis by aminoacylase present in the cytosol.
Pharmacodynamic effects

Other studies have been conducted in rats under different experimental conditions leading to increased ammonia availability (starvation, protein-free or high-protein diet). Carglumic acid was shown to decrease blood ammonia levels and increase urea levels in blood and urine, whereas the liver content of carbamoyl phosphate synthetase activators was significantly increased.

Clinical efficacy and safety

In patients with N-acetylglutamate synthase deficiency, carglumic acid was shown to induce a rapid normalisation of plasma ammonia levels, usually within 24 hours. When the treatment was instituted before any permanent brain damage, patients exhibited normal growth and psychomotor development. In patients with organic acidaemia (neonates and non-neonates), the treatment with carglumic acid induced a quick decrease of ammonia plasma levels, reducing the risk of neurological complications.

5.2 Pharmacokinetic properties

The pharmacokinetics of carglumic acid has been studied in healthy male volunteers using both radiolabelled and unlabelled product.

Absorption

After a single oral dose of 100 mg/kg body weight, approximately 30% of carglumic acid is estimated to be absorbed. At that dose-level, in 12 volunteers given carglumic acid tablets, plasma concentration peaked at 2.6 µg/mL (median; range 1.8-4.8) after 3 hours (median; range 2-4).

Distribution

The plasma elimination curve of carglumic acid is biphasic with a rapid phase over the first 12 hours after administration followed by a slow phase (terminal half-life up to 28 hours). Diffusion into erythrocytes is non-existent. Protein binding has not been determined.

Biotransformation

A proportion of carglumic acid is metabolised. It is suggested that depending on its activity, the intestinal bacterial flora may contribute to the initiation of the degradation process, thus leading to a variable extent of metabolism of the molecule. One metabolite that has been identified in the faeces is glutamic acid. Metabolites are detectable in plasma with a peak at 36-48 hours and a very slow decline (half-life around 100 hours).
The end product of carglumic acid metabolism is carbon dioxide, which is eliminated through the lungs.

Elimination

After a single oral dose of 100 mg/kg body weight, 9% of the dose is excreted unchanged in the urine and up to 60% in the faeces.

Plasma levels of carglumic acid were measured in patients of all age categories, from newborn infants to adolescents, treated with various daily doses (7–122 mg/kg/day). Their range was consistent with those measured in healthy adults, even in newborn infants. Whatever the daily dose, they were slowly declining over 15 hours to levels around 100 ng/mL.

5.3 Preclinical safety data

Safety pharmacology studies have shown that carglumic acid administered orally at doses of 250, 500, 1000 mg/kg had no statistically significant effect on respiration, central nervous system and cardiovascular system.

Carglumic acid showed no significant mutagenic activity in a battery of genotoxicity tests performed *in vitro* (Ames test, human lymphocyte metaphase analysis) and *in vivo* (micronucleus test in rat).

Single doses of carglumic acid up to 2800 mg/kg orally and 239 mg/kg intravenously did not induce any mortality or abnormal clinical signs in adult rats. In newborn rats receiving daily carglumic acid by oral gavage for 18 days as well as in young rats receiving daily carglumic acid for 26 weeks, the No Observed Effect Level (NOEL) was established at 500 mg/kg/day and the No Observed Adverse Effect Level (NOAEL) was established at 1000 mg/kg/day.

No adverse effects have been observed on male or female fertility. In rats and rabbits no evidence has been seen of embryotoxicity, foetotoxicity or teratogenicity up to maternotoxic doses leading to fifty times exposure as compared to humans in rats and seven times in rabbits. Carglumic acid is secreted in the milk of lactating rats and although developmental parameters were unaffected, there were some effects on body weight / body weight gain of pups breast-fed by dams treated with 500 mg/kg/day and a higher mortality of pups from dams treated with 2000 mg/kg/day, a dose that caused maternotoxicity. The maternal systemic exposures after 500 and 2000 mg/kg/day were twenty five times and seventy times the expected human exposure.

No carcinogenicity study has been conducted with carglumic acid.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Mannitol
Colloidal anhydrous silica
Sodium stearyl fumarate
Crospovidone type B
Copovidone K 28

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Blister (ALU/ALU) packed in a carton.

Pack size of 12 or 60 dispersible tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

7. MARKETING AUTHORISATION HOLDER

Eurocept International BV
Trapgans 5
1244 RL Ankeveen
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/17/1202/001
EU/1/17/1202/002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 June 2017
Date of latest renewal: 28 March 2022

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu.

ANNEX II

A. MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

A. MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer(s) responsible for batch release

Eurocept International BV
Trapgans 5
1244 RL Ankeveen
The Netherlands

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to restricted medical prescription (see Annex I: Summary of Product Characteristics, section 4.2).

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**

The requirements for submission of PSURs reports for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk Management Plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON 12 TABLETS

1. NAME OF THE MEDICINAL PRODUCT

Ucedane 200 mg dispersible tablets
carglumic acid

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each dispersible tablet contains 200 mg of carglumic acid.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

12 dispersible tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use only.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eurocept International BV (Lucane Pharma)
Trapgans 5
1244 RL Ankeveen
The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/17/1202/002

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Ucedane 200 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON 60 TABLETS

1. NAME OF THE MEDICINAL PRODUCT

Ucedane 200 mg dispersible tablets
carglumic acid

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each dispersible tablet contains 200 mg of carglumic acid.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

60 dispersible tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use only.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/17/1202/001

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Ucedane 200 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Ucedane 200 mg dispersible tablets
carglumic acid

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Eurocept International BV (Lucane Pharma)

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Batch

5. OTHER

B. PACKAGE LEAFLET

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 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 amino acid 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, think you may be pregnant or planning to have a baby, ask your doctor 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 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.

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 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). 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.

If you take more Ucedane than you should
Side effects such as tachycardia (increased frequency of the heart), profuse sweating, increased bronchial secretion, increased body temperature and restlessness could occur. 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 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 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. Each dispersible 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 a carton.
Pack size of 12 or 60 dispersible tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Eurocept International BV
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Manufacturer
Eurocept International BV
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This leaflet was last revised in

Other sources of information

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