



**Ketoanalogues +  
Essential Amino Acids**

**Renoguard**



600mg Film Coated Tablet

Amino acids, including combination with Polypeptides

**FORMULATION**

Each film-coated tablet contains:

Calcium-3-methyl-2-oxo-valerate.....	67mg
(α-Ketoanalogue to Isoleucine, Calcium Salt)	
Calcium-4-methyl-2-oxo-valerate.....	101mg
(α-Ketoanalogue to Leucine, Calcium Salt)	
Calcium-2-oxo-3-phenyl-propionate.....	68mg
(α-Ketoanalogue to Phenylalanine, Calcium Salt)	
Calcium-3-methyl-2-oxo-butyrate.....	86mg
(α-Ketoanalogue to Valine, Calcium Salt)	
Calcium-DL-2-hydroxy-4-(methylthio) butyrate.....	59mg
(α-Hydroxyanalogue to Methionine, Calcium Salt)	
L-Lysine-acetate.....	105mg
(equivalent to 75 mg L-Lysine)	
L-Threonine.....	53mg
L-Tryptophan.....	23mg
L-Histidine.....	38mg
L-Tyrosine.....	30mg
Total Nitrogen content/tablet .....	36mg
Calcium/Tablet.....	1.25 mmol equivalent to 0.05g

**PHARMACEUTICAL FORM**

A biconvex oblongshaped coated tablet plain on both sides

**Pharmacology**

**Mechanism of Action**

The mechanism of action of Ketoanalogue of essential amino acids is believed to involve in the prevention and therapy of damages due to faulty or deficient metabolism in chronic renal insufficiency. Ketoanalogues of essential amino acids allow the intake of essential amino acids while minimizing the amino nitrogen intake.

**Pharmacodynamics**

Renoguard tablets are administered for nutrition therapy in chronic kidney disease.

Renoguard allows the intake of essential amino acids while minimizing amino-nitrogen intake.

Following absorption, **the keto-and hydroxy-analogues are** transaminated to the corresponding essential amino acids by taking nitrogen from non-essential amino acids, thereby decreasing the formation of urea by re-using the amino group. Hence, the accumulation of uraemic toxins is reduced. Keto and hydroxy acids do not induce hyperfiltration of the residual nephrons. Ketoacid containing supplements exert a positive effect on renal hyperphosphataemia and secondary hyperparathyroidism. Moreover, renal osteodystrophy may be improved. The use of Renoguard in combination with a very low protein diet allows to reduce nitrogen intake while preventing the deleterious consequences of inadequate dietary protein intake and malnutrition.

**Pharmacokinetics**

The plasma Kinetics of amino acids and their integration in metabolic pathways are well established. It should nevertheless be noted that in uremic patients, the plasma disturbances do not seem to depend on digestive amino acid intake, and that the post absorptive kinetics seems to be disturbed very early in the development of the diseases.

**INDICATION**

Prevention and therapy of damage due to faulty or deficient protein metabolism in chronic renal insufficiency in connection with limited protein in food of 40 g per day and less in patients with glomerular filtration rate (GFR) below 25 mL/min

**DOSAGE AND ADMINISTRATION**

+For oral use: Swallow whole. This dosage applies to adults (>70 kg body weight) with recommended dose of Ketoanalogues of essential amino acids in adult > 70 kg body weight are 4-8 tab 3 times daily

+Ketoanalogues of essential amino acids tablets are given as long as GFR is between 5 and 50 mL/minute. Simultaneously food should contain 40 g/day protein or less (adults). Therapy should be prescribed by a physician experienced in the management of chronic renal disease

+Liver Disease/ Renal Impairment - No dosage adjustment is necessary

+The tablets should be taken in the order of succession stated on the package everyday at about regularly the same time of the day as prescribed by the physician

**CONTRAINDICATIONS**

+ Known to be hypersensitive or who have previously had a hypersensitivity to one or more amino acids or idiosyncratic reaction to Ketoanalogues of essential amino acids

- + Severe liver diseases and hepaticcoma
- + Metabolic disorders associated with impaired nitrogen utilization
- + Hypercalcemia, disturbed amino acid metabolism

**WARNINGS**

Ketoanalogues of essential amino acids should be used with caution in the following patients

- + With severe heart disease
- + Known to be hypersensitive or who have previously had a hypersensitivity to one

**PRECAUTIONS**

- + Ensure the sufficient supply of calories
- + Safe, effective use of nutrition in chronic renal diseases requires knowledge of nutrition as well as clinical expertise in recognition and treatment of complications which can occur
- + Regular evaluation of the serum calcium level and laboratory determinations are necessary for proper monitoring of patients undergoing treatment with Ketoanalogues of essential amino acids
- + Objective therapy is intended to provide nutritional support for a limited period of time. If a patient requires an extended period of nutritional support, parenteral regimens should include non-protein calories adequate for weight maintenance

**PREGNANCY AND LACTATION**

There are no adequate data from the use of Renoguard in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or post natal development. Caution should be exercised when prescribing to pregnant women. No experience has been made so far with the use during lactation.

**ADVERSE REACTIONS**

- + Hypercalcemia may develop
- + Generalized flushing, fever and nausea have been reported in the literature during the administration of amino acids
- + At the beginning of therapy, fever, nausea, vomiting, abdominal pain, diarrhea and fatigue may occur, those reactions are usually mild and disappear within a few weeks even if treatment is continued

**DRUG INTERACTIONS**

When Ketoanalogues of essential amino acids is used as one of the drugs in multiple regimens, the toxicity of Ketoanalogues of essential amino acids should be borne in mind in the selection and dosage of drugs with similar mechanism of actions. The addition of other drugs can necessitate changes and dose alterations

Simultaneous administration of medicaments containing calcium may lead to pathological increase of serum calcium level or intensification. In order not to interfere with absorption, do not take drugs together with Ketoanalogues that come from sparingly soluble compounds with calcium (e.g. tetracycline)

**OVERDOSAGE**

The acute reaction to an overdose of Ketoanalogues of essential amino acids would probably include hypotension, fever, rapid pulse and general symptoms of shock. Treatment is purely symptomatic. There is no specific antidote to Ketoanalogues of essential amino acids

**CAUTION**

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription

For suspected adverse drug reaction, report to the FDA: [www.fda.gov](http://www.fda.gov)

**STORAGE**

Store at temperatures not exceeding 30°C  
Store in a dry place and protect from light  
Keep out of reach of children

**AVAILABILITY**

Foilstrip x 10's (Box of 100's)

Registration Number: DRP-4845  
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