



## Ketoanalogues + Essential Amino Acids

### Renoguard 600 mg Film-Coated Tablet Renal Nutrition Therapy

#### FORMULATION

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

#### 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

Ketoanalogues of essential amino acids act to normalization of metabolic processes. Ketone bodies amino acids in total transamination to the L-amino acids, splitting with the urea. Nitrogen promotes recycling products exchange, anabolism proteins while reducing the urea concentration in serum. Ketoanalogues of essential amino acids also improve nitrogen exchange. It reduces ion concentrations of potassium, magnesium and phosphate.

##### 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 disease.

#### 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 or 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.
- + Renal failure
- + Severe liver diseases and hepatic coma
- + 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.

#### ADVERSE REACTIONS

- + Hypercalcaemia 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 continues.

#### 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.

#### STORAGE

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

#### AVAILABILITY

Foil strip x 10's (Box of 100's)

Manufactured by:

**PT. IKAPHARMINDO PUTRAMAS**  
Jl. Pulogadung Raya No. 29 - KIP  
Jakarta Timur 13930 - Indonesia

Imported and Distributed by:

**NATRAPHARM, INC.**  
The Patriot Building  
Km. 18 West Service Road  
SLEX, Sucat, Parafique City