NefroGard

Tablet

Composition:

Each film coated tablet contains :

Calcium-3-methyl-2-oxo-valerate	67 mg
(α-ketoanalogue to isoleucine , calcium salt)	
Calcium-4-methyl-2-oxo-valerate	101 mg
(α-ketoanalogue to leucine , calcium salt)	
Calcium-2-oxo-3-phenylpropionate	68 mg
(α-ketoanalogue to phenylalanine , calcium salt)	
Calcium-3-methyl-2-oxo-butyrate	86 mg
(α-ketoanalogue to valine , calcium salt)	
Calcium-dl-2-hydroxy-4(methylthio) butyrate	59 mg
(α-hydroxyanalogue to methionine , calcium salt)	
Lysine acetate u.s.p.	105 mg
(eq to lysine 75 mg.)	
L-threonine u.s.p.	53 mg
L-tryptophan u.s.p.	23 mg
L-histidine u.s.p	38 mg
L-tyrosine u.s.p.	30 mg
Total nitrogen content per tablet	36 mg
Calcium content per tablet	1.25 mmol=0.05 g

Pharmacokinetic properties:

The plasma kinetics of amino acids and their integration in the metabolic pathways are well established. It should nevertheless be noted that in uraemic patients, the cause of the changed plasma levels, which occur frequently in these patients, does not seem to be the absorption of the supplied amino acids, i. e. the absorption itself is not disturbed. The changed plasma levels seem to be due to impaired post-absorptive kinetics, which can be

detected in a very early stage of the disease. In healthy individuals, the plasma levels of ketoacids increase within 10 min after oral administration. Increases of up to the 5-fold the baseline levels are achieved. Peak levels occur within 20-60 min, and after 90 min levels stabilise in the range of the base levels. Gastrointestinal absorption is thus very rapid. The simultaneous increases in the levels of the ketoacids and the corresponding amino acids show that the ketoacids are transaminated very rapidly. Due to the physiological utilisation pathways of ketoacids in the body it is likely that exogenously supplied ketoacids are very rapidly integrated into the metabolic cycles. Ketoacids follow the same catabolic pathways as classical amino acids. No specific study on ketoacid excretion has been performed to date.

Mechanism of Action

Prevention and treatment of damages due to faulty or deficient protein metabolism in chronic kidney disease in connection with a limited dietary protein intake of 40 g/day or less (adult). Usually this applies to patients whose glomerular filtration rate (GFR) is less than 25 mL/min.

- Nitrogen free analogues of essential amino acids
- Administered for nutrition therapy in chronic kidney disease.
- Relieves uremic states, improve nutritional states, slow down illness progression and protect kidney functions
- With low protein diets can delay or prevent dialysis by relieving metabolic complications

Other pharmacodynamic properties:

Nefrogard® tablets are administered for nutrition therapy in chronic kidney disease. Nefrogard® allows the intake of essential amino acids while minimising the 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 Nefrogard® 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.

Indication:

Prevention & therapy of kidney damage in CKD with protein restricted diet.

Contraindication:

Hypersensitivity to the active substances or to any of the excipients

- Hypercalcaemia

- Disturbed amino acid metabolism

Drug Interaction:

Concomitant administration of calcium-containing drugs may cause or aggravate elevated serum calcium levels. Drugs that form soluble compounds with calcium (e.g. tetracyclines, quinolines such as ciprofloxacin and norfloxacin as well as drugs containing iron, fluoride or estramustine) should not be taken at the same time with Nefrogard® to avoid disturbed absorption of the active substances. An interval of at least two hours should elapse between the ingestion of Nefrogard® and these drugs.

Adverse effects:

If hypercalcaemia occurs, the intake of vitamin D should be reduced. In case of persisting hypercalcaemia, the dose of Nefrogard® as well as the intake of any other calcium sources has to be reduced.

Warnings and Precautions:

The serum calcium level should be monitored regularly. Ensure sufficient calorie intake. No experience has been gained so far with the administration in paediatric patients. In the presence of hereditary phenylketonuria, attention should be given to the fact that Nefrogard® contains phenylalanine. Monitoring of the serum phosphate levels is needed in case of concomitant administration of aluminium hydroxide.

Use in special population:

1. **Pediatric:** Safety and effectiveness of Nefrogard in pediatric patients have not been established.
2. **Geriatric:** Safety and effectiveness of Nefrogard in geriatric patients have not been established.
3. **Liver impairment:** There is limited information available on the use of Nefrogard Tablet in patients with liver disease. Please consult your doctor.
4. **Renal failure:** Nefrogard Tablet is safe to use in patients with kidney disease. Limited data available suggests that dose adjustment of Nefrogard Tablet may not be needed in these patients. Please consult doctor.

5. **Pregnancy and lactation:** Human and animal studies are not available for safety and efficacy in pregnancy and breast feeding. Please consult doctor before use.

Dosage:

As directed by physician.

Presentation:

Nefrogard is available as blister pack of 10 tablets.

Storage and handling:

Keep in cool and dry place. Protect from light. Keep away from children.