KETOANALOGUES + ESSENTIAL AMINO ACIDS

Rx

NEFROTEIN

Film-Coated Tablet
Renal Nutrition Therapy

FORMULATION:
Each film-coated tablet contains:
Calcium-4-methyl-2-oxo-valerate .....101 mg
(α-ketoanalogue to leucine, calcium salt)
Calcium-3-methyl-2-oxo-butyrate .....86 mg
(α-ketoanalogue to valine, calcium salt)
Calcium-2-oxo-3-phenylpropionate .....68 mg
(α-ketoanalogue to phenylalanine, calcium salt)
Calcium-3-methyl-2-oxo-valerate .....67 mg
(α-ketoanalogue to isoleucine, calcium salt)
Calcium-DL-2-hydroxy-4-(methylthio) butyrate .....59 mg
(α-ketoanalogue to methionine, calcium salt)
L-Lysine Acetate .....105 mg
L-Threonine .....53 mg
L-Histidine .....38 mg
L-Tyrosine .....30 mg
L-Tryptophan .....23 mg
Total Nitrogen Content.....36 mg
Calcium.....(1.25 mmol)= 0.05 g
Colour: Quinoline Yellow & Titanium Dioxide.

PRODUCT DESCRIPTION:
Yellow coloured, capsule shaped both sides plain film-coated tablet.

PHARMACODYNAMICS:
Ketoanalogues + Essential Amino Acids used for nutrition therapy in chronic kidney disease.
In absorption process, 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.
Ketoanalogues + Essential Amino Acids do not induce hyperfiltration of the residual nephrons. Ketoanalogues + Essential Amino Acids containing supplements exert a positive effect on renal hyperphosphataemia and secondary hyperparathyroidism. Moreover, renal osteodystrophy may be improved. The use of Ketoanalogues + Essential Amino Acids 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 essential 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.
Gastrointestinal absorption is thus very rapid. The simultaneous increases in the levels of the Ketoanalogues + Essential Amino Acids and the corresponding amino acids show that the Ketoanalogues + Essential Amino Acids are transaminated very rapidly. Due to the physiological utilization pathways of Ketoanalogues + Essential Amino Acids in the body, it is likely that exogenously supplied Ketoanalogues + Essential Amino Acids are very rapidly integrated into the metabolic cycles. Ketoacids follow the same catabolic pathways as classical amino acids. No specific study on Ketoanalogues + Essential Amino Acids excretion has been performed to date.

INDICATIONS:
For prevention and therapy of damages due to faulty or deficient protein metabolism in chronic renal insufficiency in connection with limited protein food of 40 grams per day (for adults) and less. Usually, this applies to patients whose glomerular filtration rate (GFR) is less than 25 mL/min.

DOSAGE AND ADMINISTRATION:
If not otherwise prescribed, the dose for adults (70 kg body weight) is 4 to 8 tablets three times daily during meals. The tablets must not be chewed. Ingestion during meals facilitates proper absorption and the metabolism into the corresponding amino acids. There is no experience in children.
For oral use.
Or as prescribed by the physician.

DURATION OF ADMINISTRATION:
The product is administered as long as the glomerular filtration rate (GFR) is below 25 mL/min, and concomitantly, dietary protein is restricted to 40 g/day or less (adult).

CONTRAINDICATIONS:
-Hypersensitivity to the active substances or to any of the excipients.
-Hypercalcaemia
-Disturbed amino acid metabolism.

ADVERSE DRUG REACTIONS:
Metabolism and nutrition disorders:
Very rare: hypercalcaemia.
If hypercalcaemia occurs, the intake of vitamin D should be reduced. In case of persisting hypercalcaemia, the dose of the product as well as the intake of any other calcium sources has to be reduced.

DRUG INTERACTIONS:
Concomitant administration of calcium-containing drugs may cause or aggravate elevated serum calcium levels.
Drugs that form hardly soluble compounds with calcium (e.g., tetracyclines, quinolones such as Ciprofloxacin and Norfloxacin as well as drugs containing iron, fluoride or estramustine) should not be taken at the same time with the products to avoid disturbed absorption of the active substances. An interval of at least two hours should elapse between the ingestion of the product and other drugs.
The susceptibility to cardioactive glycosides, and hence the risk for arrhythmia will increase if the product produces elevated serum calcium levels.
Uraemic symptoms improve under therapy with the product. Thus, in case of aluminum hydrochloride administration, the dose of these drugs has to be reduced if necessary. Serum phosphate levels should be monitored for a decrease.

PRECAUTION:
Do not use the product after expiry date.

PREGNANCY AND LACTATION:
No experience has been made so far with the application in pregnancy and lactation.

OVERDOSE AND TREATMENT:
No specific information is available on the treatment of overdose with Ketoanalogues + Essential Amino Acids film-coated tablet.

CAUTION:
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.
Seek medical attention immediately at the first sign of any adverse drug reaction.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

AVAILABILITY:
Aluminum Foil Strip Pack of 10's (Box of 100's)

DRP-6051-15
Date of First Authorization: June 28, 2021
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Manufactured by:
STALLION LABORATORIES PVT. LTD.
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